



Real-world effectiveness after initiating fremanezumab treatment in Brazilian patients with episodic and chronic migraine

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Background

Migraine is a debilitating condition, estimated to affect 30 million people in Brazil. Prevention may be considered for both episodic (EM) and chronic (CM) migraine and represents a real challenge in patient management. Fremanezumab, a fully humanized monoclonal antibody, is a specific migraine treatment directed against CGRP ligand. Regulatory approval for this molecule in Brazil occurred in December 2019, becoming an option of treatment in our country. Given the relatively recent approval, studies and publications that address real-world data on the use of Fremanezumab are needed, which we will refer to in this study.

Methods

This is real-world, retrospective chart review study that assessed demographic and clinical aspects of 170 Fremanezumab treated patients. The safety of the drug was evaluated to all patients who received at least 1 Fremanezumab treatment, and the effectiveness for EM and CM patients that completed 12 weeks of treatment based in monthly headache days (MHD) pre- and post-Fremanezumab. Data was obtained from two tertiary neurology services, in São Paulo, southeast region, and Fortaleza, northeast region of Brazil, between 2021 and 2022. Inclusion criteria were a physician diagnosis of EM or CM, age ≥ 18 years at the time of first Fremanezumab initiation, ≥ 1 dose of Fremanezumab treatment; ≥ 1 follow-up visit since first initiation; and measurement of monthly headache days (MHD at initiation and after 12 weeks of medication use). Efficacy measures were considered to patients that presented $\geq 50\%$ improvement, $\geq 75\%$ improvement or $\geq 100\%$ after 12 weeks in MHD after Fremanezumab treatment initiation.

Results

There were no differences between of the two centers population. Of the total sample, women represent 76.5%, and the mean age was 46.04 (± 13.94) years. The average age of migraine onset was 15.7 (± 9.28) years, and the mean age when receiving the first Fremanezumab treatment was 45.08 (± 14.11) years. The time of CM in years before initiating Fremanezumab was 8.87 (± 7.65) years. All this sample had the medication monthly. The improvement analyses considered 102/170 patients, 60% of the sample, who have completed the 12 weeks follow-up visit. Overall, 65% of the patients showed an improvement after this period of treatment. The mean number of MHD at the initiation of the treatment was 19.31, falling to 8.89 at the first month and 6.94 at the third month. When considering the 12 weeks follow-up visit 81.4% of the sample improved $\geq 50\%$, 35.3% improved $\geq 75\%$, and 2.9% presented a 100% resolution of MHD. Side effects observed with Fremanezumab use were none to 65% of patients, limited local pain in 30.3%, site injection erythema in 9.9%, flu-like symptoms, and intestinal constipation 0.7% each. From the total patients of this sample only 3 patients interrupted the treatment because of side effects: 1 with local erythema, 1 with flu-like symptoms, and 1 with intestinal constipation.

Conclusion

For this Brazilian sample of EM or CM patients Fremanezumab proved to be a very efficient, safety, and well tolerated option for migraine treatment. Real-world evidence studies are valid and useful tools to understand the behavior of patients in many life scenarios. Our findings reassure the pattern of response to Fremanezumab in everyday migraine treatment worldwide.