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BRIEF COMMUNICATION

Erenumab in 159 high frequency and chronic migraine patients: real-life results from the Bologna Headache Center

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Migraine is one of the most prevalent and disabling conditions worldwide. Treatment of migraine can involve both acute and preventive interventions. Patients with frequent headache may require both approaches. Acute treatment is aimed at aborting the headache attack, whereas preventive treatment is geared toward reducing the frequency and severity of attacks. Monoclonal antibodies against CGRP (mAbs) are a novel therapeutic preventive option for patients with migraine [1]. Among mAbs, erenumab selectively targets the CGRP receptor. Randomized controlled trials have proven efficacy and safety of erenumab as preventive treatment for both episodic and chronic migraine (CM); however, real-life studies are still needed to confirm these results in everyday clinical practice.

We report preliminary result of a prospective study that evaluates effectiveness and safety of erenumab in a cohort of high-frequency episodic migraine (HFEM) and CM patients in real life. Patients were selected at our Tertiary Headache Centre in Bologna, Italy, between May 2019 and April 2020. Inclusion criteria for eligibility in the study were the following: (i) patients with HFEM (8–14 headache days/month) or CM (≥ 15 headache days/month) with or without MOH, defined according to ICHD-3; (ii) history of more than two migraine prophylactic treatment failures. We excluded patients who were pregnant or breastfeeding as well as patients with major cardiovascular or cerebrovascular events. All eligible patients received treatment with erenumab once every 4 weeks. Erenumab dose was 70 mg for the first 2 months; subsequently, according to the reduction in monthly migraine days (MMDs), we decided whether to continue with the erenumab 70 mg or to switch to erenumab 140 mg.

Our primary endpoints were to assess the percentage of patients that reported a reduction of at least 50% in MMD (50% responder rate) at 3 and at 6 months, and to evaluate treatment safety.

Our secondary endpoints included evaluating changes in MMD, monthly pain medication intake (MPMI), and disability scores measured with Headache Impact Test-6 (HIT-6), as well as assessing adherence to treatment during the study period.

The study was conducted in agreement with principles of good clinical practice, and the study protocol was approved by the Local Ethics Committee of the local health service of Bologna, Italy (n. CE 20073).

The statistical analysis was performed with IBM SPSS Statistics Version 26. Categorical data were reported as percentages and compared with chi-squared test, while continuous data were reported as mean and standard deviation (SD) and compared with either Student *t* test or paired *t* test. We set statistical significance at $p < 0.05$ using one-tailed tests.

In the study period, 159 patients (120 F, 39 M; mean age 50.23 ± 9.4) received at least one erenumab dose. Among them, 122 patients (76.7%) had CM and 37 (23.3%) had HFEM. Most of our CM patients (111/122, 91%) also suffered from MOH. The overused agents were as follows: triptans (N = 124; 77.9%), non-steroidal anti-inflammatory drugs (N = 74; 46.5%), combinations (N = 79; 49.7%), and opioid medication (N = 1; 0.6%). Mean migraine duration was 33.6 ± 11.8 years. Mean number of previous pharmacological prophylactic failures was 6.9 ± 2.7. Most patients (78%, 124/159 patients) had formerly undergone treatment with onabotulinumtoxin-A. At baseline MMD was 20.3 ± 7.2, MPMI was 30.4 ± 23.9, and HIT-6 mean score was 65.1 ± 6.7 (Table 1).

After 1 month of treatment, MMD decreased to 15.5 ± 8.3 and MPMI to 18.7 ± 13.8, both significantly ($p < 0.001$).

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Table 1 Baseline characteristics of the population study

Baseline characteristics	Total pts: 159
Female, *n* (%)	120 (75.5%)
Age, years (mean-SD)	50.23 ± 9.4
Migraine duration, years (mean-SD)	33.6 ± 11.8
Episodic migraine, *n* (%)	37 (23.3)
Chronic migraine, *n* (%)	122 (76.7)
MOH, *n* (%)	111 (69.8)
No. of previous pharmacological treatments failed (mean-SD)	6.9 ± 2.7
Monthly migraine days (mean-SD)	20.3 ± 7.2
Monthly pain medication intake (mean-SD)	30.4 ± 23.9
HIT-6 score (mean-SD)	65.1 ± 6.7
Headache intensity: NRS (median ± IQR)	7 ± 2

Eighty-one (50.9%) patients received three doses of erenumab. Among them, 74.1% had switched to 140 mg dose of erenumab. Overall, MMD decreased to 14.3 ± 8.6 and MMPI to 17.8 ± 15.2. Fifty percent responder rate was 34.6% (28/81). Among the responders, MMD changed from 20 ± 6 to 6.7 ± 3.1 ($p < 0.001$), while MPMI decreased from 26.9 ± 12.5 to 7.9 ± 4.5 ($p < 0.001$) and HIT-6 mean scores decreased from 66.7 ± 4.7 to 58.9 ± 8.4 ($p < 0.001$). Comparing baseline responders vs. non-responders' epidemiological and migraine-related features, such as disease duration, frequency of attacks, and number of previous prophylactic failures, we found no difference between the two groups.

Forty (26.8%) patients received six doses of erenumab. Among these patients, MMD was 14.3 ± 8.6 and MPMI 17.8 ± 15.2. The 50% responder rate was 27.5% (11/40).

During the study period, minor adverse events were reported by 53/159 (33.3%) patients. Constipation was the main adverse event reported by 20 patients. No serious treatment-related adverse events were reported. Treatment was stopped in 11 patients because of ineffectiveness after the third dose. Four patients were drop-outs.

Our preliminary results confirm the effectiveness and safety of erenumab, even in a cohort of patients with HFEM and CM with multiple preventive treatment failures.

We found a significant reduction in attack frequency, medication intake, and migraine-related disability. Such improvement is maximum after the first administration of erenumab and is maintained through the entire follow-up period. The 50% responder rate, both at 3 and 6 months, was achieved in about one-third of patients. Our results are similar to those reported by RCTs, ranging from 30 to 50% [1]. The 50% responder rate reported in real-life studies varied, depending on the study populations (episodic vs. chronic) and the study duration [2, 3]. A recent real-life study evaluating erenumab in a cohort of both episodic and CM patients up to 6-month treatment found a 50% reduction in headache frequency in about 70% of patients [3]. The higher rate of response compared with ours may be due to the higher number of previous preventive treatment failure in our cohort.

Our results confirm the safety of the treatment. Accordingly, we observed only mild adverse events, mostly constipation, as previously reported. Adherence to erenumab treatment in this study is very high, since we registered only four drop-outs.

The future challenge will be to confirm these results in a larger number of patients and to confirm the sustained effect over the time. In this perspective, multicenter real-life results are warranted.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants including the study.

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