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A Retrospective Analysis of Migraine Prophylaxis with Anti-CGRP Monoclonal Antibodies at the Hospital of Lithuanian University of Health Sciences Kaunas Clinics

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Summary. *Background.* Migraine is a primary headache disorder described by episodic attacks that can progress to chronic migraine. Preventive treatment of anti-calcitonin gene-related peptide monoclonal antibodies (anti-CGRP mAbs) is currently being widely investigated worldwide.

Materials and methods. A total of 85 patients with migraine were enrolled in a retrospective study conducted in 2019–2021. Demographic and clinical data were collected and analyzed. Subjects were divided into groups by migraine course: chronic migraine (CM) and episodic migraine (EM), and according to the medicine used (erenumab, fremanezumab). Treatment efficacy was assessed at 3 and 6 months after the start of treatment. A reduction of 50% in monthly headache days (MHDs) was considered a good response. Statistical analysis was performed using IBM SPSS statistics 27.0, the ^{2} test of homogeneity, Fisher's exact, Student's t, and Mann-Whitney tests.

Results. Of the 85 migraine patients, 75 (88.2%) were women. EM was diagnosed in 33 (38.8%) and CM in 52 (61.2%) patients. After treatment, the number of MHDs was significantly reduced in both anti-CGRP mAbs therapy groups ($p<0.001$). The response to anti-CGRP mAbs was similar between the EM and CM groups. A slightly better response was achieved with fremanezumab than erenumab (83.3% vs. 73.1% at 3 months; 83.3% vs. 65.7% at 6 months), but the difference was not significant ($p=0.541$; $p=0.149$). In 24 (58.5%) patients initially given 70 mg erenumab, after a median follow-up of 3 months (interquartile range: 2-6) it was decided to increase the dose of erenumab to 140 mg due to insufficient effect. The initial dose was increased more often in patients with chronic migraine ($p=0.027$).

Conclusions. Erenumab and fremanezumab are equally effective and equivalent for both migraine types. It was observed that more than half of the patients required a dose increase when treated with erenumab 70 mg, especially in CM group.

Keywords: chronic, episodic migraine, erenumab, fremanezumab, treatment.

INTRODUCTION

Migraine is a primary headache disease characterized by episodic attacks that can progress to chronic migraine (CM) [1]. CM has a high disability rate, and the management of the disease is still a big challenge for clinicians [2]. For a long time, there were no specific medications to prevent migraine. It was treated only with medications from different classes, including beta-blockers, antidepressants, anticonvulsants, which were developed to cure diseases other than migraines. However, a recently published study shows that 28.2% of migraine patients treated with non-specific migraine prophylaxis discontinue treatment within 6 months, mainly due to side effects [3]. The high prevalence of migraine, low prior treatment effectiveness, and migraine-related disability have played an important

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role in finding specific therapeutics medication for migraine prevention.

The calcitonin gene-related peptide (CGRP) antagonists were approved in 2018 by the United States Food and Drug Administration and the European Medicines Agency. The recent introduction of monoclonal antibodies against the CGRP pathway has widened the spectrum of treatment options available for patients with CM and episodic migraine (EM) [4, 5]. Anti-CGRP monoclonal antibodies (mAbs) for migraine prevention reached the Lithuanian market in December 2018. Reimbursement of the first drug in this class, erenumab, started in May 2020. The second medication, fremanezumab, has been reimbursed since January 2021. In Lithuania, anti-CGRP mAbs (erenumab, fremanezumab) is usually given once a month and is administered subcutaneously. Primary efficacy should be evaluated at 3 and 6 months. It is recommended to consider the need to continue treatment after 12 months [6]. Erenumab can be administered at a dose of 70 mg or 140 mg, but if a sufficient clinical effect is not obtained, a lower dose can be increased to 140 mg [7]. Fremanezumab can be given as a monthly dose of 225 mg or quarterly at three times higher dose (675 mg) [8].

The prophylactic treatment of migraine with anti-CGRP mAbs has only recently been introduced, and there is a growing body of evidence demonstrating their efficacy both in clinical trials and in daily practice. However, there are few studies evaluating the effectiveness of erenumab and fremanezumab in Lithuania.

AIM

To evaluate and compare the efficacy and side-effects of treatment with anti-CGRP mAbs (erenumab, fremanezumab) in patients with CM and EM.

MATERIALS AND METHODS

A total of 85 migraine patients who attended the Neurology Clinic of the Hospital of Lithuanian University of Health Sciences Kaunas Clinics between September 2019 and December 2021 were included in the analysis. The study was authorized by the Bioethics Centre under No BEC-MF-84.

Demographic and clinical data were collected by reviewing outpatient visit records: gender and age of the patient, duration of illness, symptoms of aura, prior preventive treatment, anti-CGRP mAbs (erenumab, fremanezumab), monthly headache days (MHDs) before anti-CGRP mAbs and at 3 and 6 months, the dose of erenumab (70 or 140 mg), dose change and reasons for the change of anti-CGRP mAbs, adverse effects of anti-CGRP mAbs. No data were collected on medication overuse, number of migraine days, monthly migraine-specific medication days, transition from CM to EM. The subjects were divided into two groups depending on the course of the disease: EM or CM. CM group consisted of patients with headaches lasting 15 days/month, 3 months or more. EM group included patients who experienced headaches for 0-14 days/month [9]. The subjects were also divided into groups according to the type of anti-CGRP mAbs used for prophylactic treatment of migraine (erenumab or fremanezumab). The efficacy of preventive migraine treatment with anti-CGRP mAbs was assessed 3 and 6 months after the start of treatment. MHDs reduction of 50% was considered a good response to treatment. If MHDs decreased by <50%, a sufficient response was not achieved. Cases where treatment was discontinued due to adverse medications reactions were included separately.

Inclusion criteria:
Subjects aged 18 years or older who had received prophylactic migraine treatment with anti-CGRP mAbs for at least 6 months and whose detailed medical records were found at baseline of anti-CGRP mAbs at 3 and 6 months after the start of treatment. Cases where treatment was discontinued earlier than 6 months due to an adverse event or insufficient response were also included.

Exclusion criteria:
Patients were excluded if they were under 18 years of age and it was not possible to evaluate the effect of treatment after 3 and 6 months.

Statistical analysis

Statistical analysis of the data was performed using SPSS (Statistical Package for the Social Sciences) Statistics 27.0 software. The results are presented as percentages, mean with standard deviation (±SD), median with interquartile range (IQR). Analysis of qualitative data was performed using ^{2} test of homogeneity and Fisher's exact test. Quantitative data were analyzed using Student's t-test and Mann-Whitney U-test. The difference was considered statistically significant at $p<0.05$.

RESULTS

A total of 85 migraine patients were included in the study; 75 (88.2%) were women and 10 (11.8%) were men. The mean age of migraineurs was 43.4 years (±11.8). Overall, the disease duration median was 19 years (IQR: 8-32). A detailed comparison of major patient characteristics between EM and CM is shown in Table. Before treatment with anti-CGRP mAbs, 63.5% of patients received other prophylactic treatment (31.8% of patients were treated with topiramate, 20.0% with propranolol, 20.0% with amitriptyline, 9.4% with pregabalin, 7.1% with valproic acid, and 5.9% with escitalopram). Prophylactic treatment with single drug was tried by 32.9% of patients, two or

Table. **Comparison of patients with chronic and episodic migraine**

	Chronic migraine (n=52)	Episodic migraine (n=33)	p value
Gender women, n (%) men, n (%)	 46 (61.3) 6 (60.0)	 29 (38.7) 4 (40.0)	0.935
Age, years mean (±SD)	45.6 (±12.2)	39.9 (±10.4)	0.027
Migraines with aura, n (%)	18 (34.6)	13 (39.4)	0.656
Duration of illness, years median (IQR)	25 (10-33.25)	14.5 (5.75-22.75)	0.011

Abbreviations: IQR – interquartile range; SD – standard deviation; n – number of individuals.

more drugs by 30.6% of patients. 30 (55.6%) patients had no response and 13 (24.1%) patients experienced adverse effects (drowsiness, dizziness, bradycardia, hypotension, sleep disturbances, joint pains) that led to the withdrawal of previously used drugs.

When comparing MHDs between EM and CM patients before anti-CGRP mAbs and after starting anti-CGRP mAbs at 3 and 6 months, the number of MHDs remained significantly higher in CM patients (p<0.001, p<0.001, and p=0.020, respectively), but the decrease was proportionally similar in both groups (Fig. 1). As demonstrated in Figure 2, although slightly better treatment outcomes were observed in the EM group (84.8% of patients achieving a good response to anti-CGRP mAbs at 3 months after starting treatment) than in the CM group (69.2%), the difference was not statistically significant (p=0.319). After 6 months of treatment, the difference between the groups decreased (75.8% vs. 65.4%, p=0.727) (Fig. 2). Over the entire follow-up period, the response rate in the CM group (-3.8%) decreased less than in the EM group (-9%).

A total of 67 (78.8%) patients received erenumab as the first anti-CGRP mAbs for migraine prophylaxis, and 18 (21.2%) patients received fremanezumab (monthly). In terms of MHDs before starting anti-CGRP mAbs,

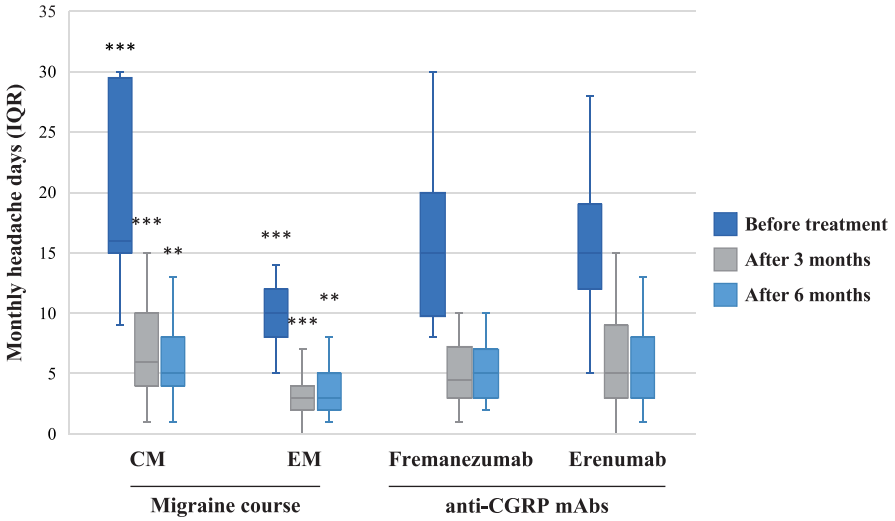

Fig. 1. **Changes of MHDs before treatment, at 3 and 6 months**
Mann-Whitney U-test was used to compare monthly headache days (MHDs) between chronic migraine (CM) and episodic migraine (EM) groups, fremanezumab and erenumab. All bars represent median (interquartile range (IQR)), minimal and maximal values.
***p<0.001 comparing MHDs between CM and EM groups before anti-calcitonin gene-related peptide monoclonal antibodies (anti-CGRP mAbs), at 3 months, **p=0.020 comparing MHDs between CM and EM groups using anti-CGRP mAbs at 6 months.

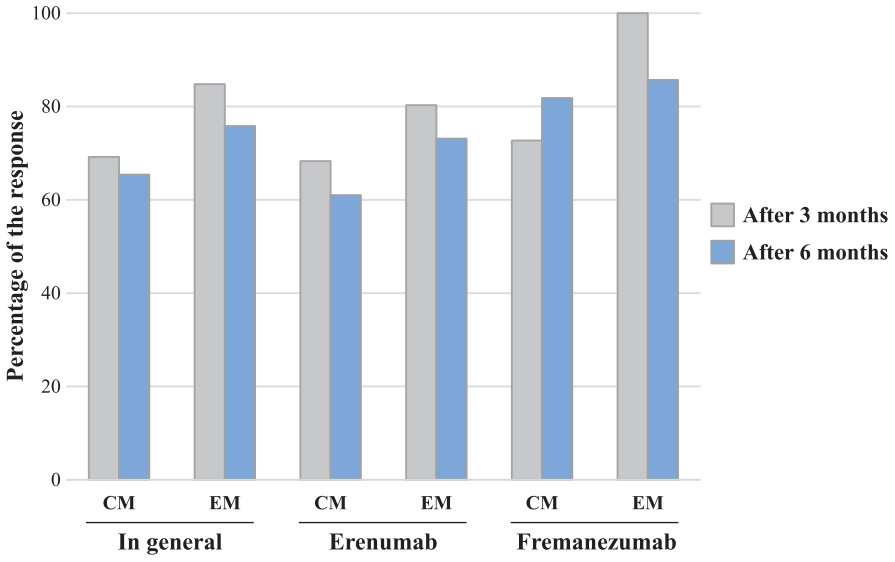

Fig. 2. **Comparison of MHDs reduction of 50% or greater at 3 and 6 months**
The ^{2} test of homogeneity was used to compare monthly headache days (MHDs) reduction of 50% or greater between fremanezumab and erenumab groups. All columns represent percentage of the response (p>0.05). Abbreviations: CM – chronic migraine; EM – episodic migraine.

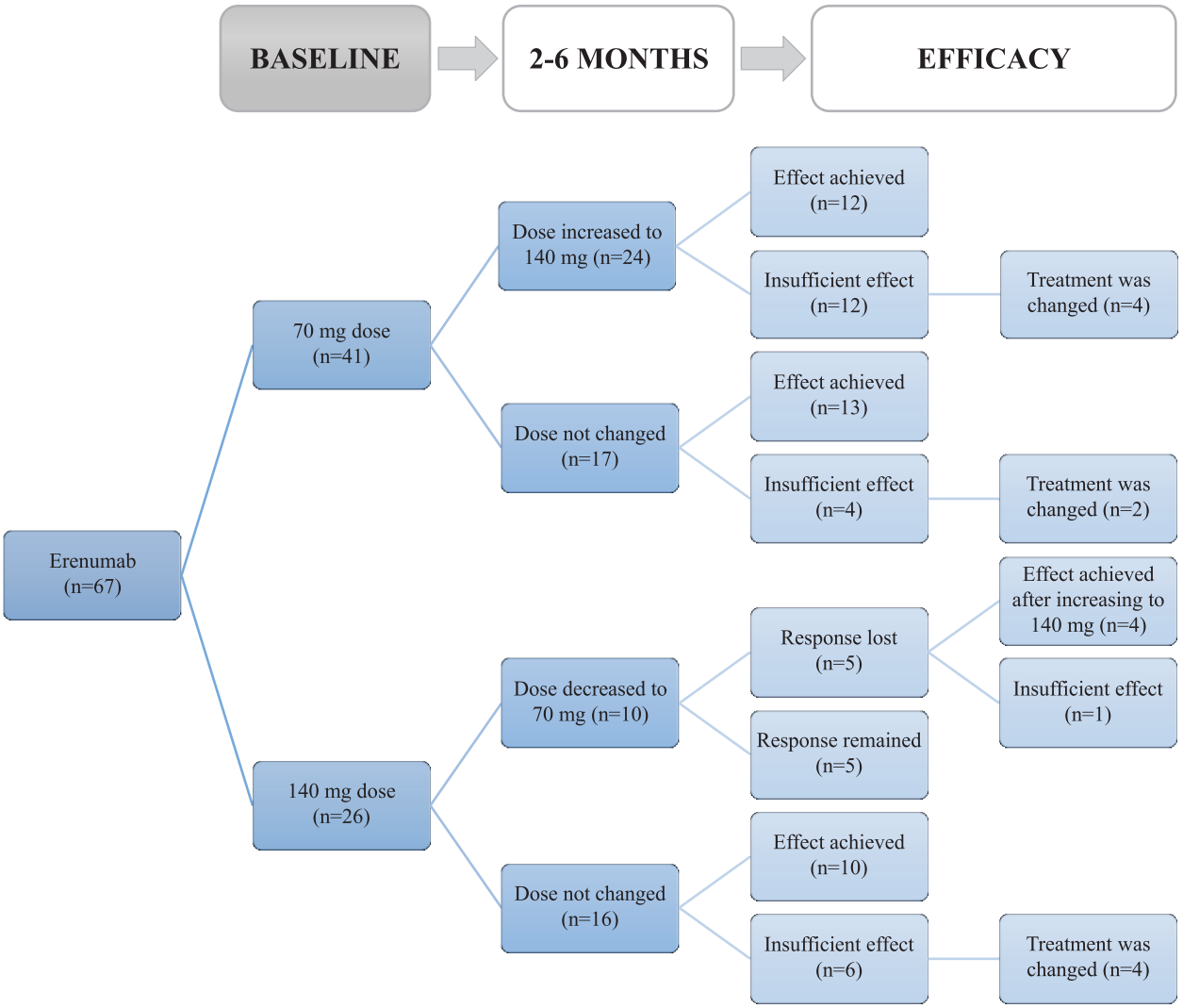

Fig. 3. **Changes of erenumab doses and assessment of effects after 2-6 months**

there was no significant difference between erenumab and fremanezumab groups (median 15 days, p=0.883). Similarly, the groups did not differ in total duration of disease (median 18 (IQR 7-30.75) vs. 27 (IQR 10-31.75), p=0.528) and presence of aura symptoms (37.3 vs. 33.3%, p=0.755). As to anti-CGRP mAbs efficacy at 3 months, the response rate was slightly better in the fremanezumab group than in the erenumab group (83.3% vs. 73.1% of patients, respectively), but the difference was not significant (p=0.541) (Fig. 2). At 6 months after initiation of treatment, the response rate to fremanezumab remained the same (83.3%), while a decrease was observed in the erenumab group (65.7%); however, the difference between the groups did not reach a statistically significant level (p=0.149) (Fig. 2).

Erenumab was initiated at a dose of 70 mg in 41 patients and 140 mg in 26 patients. In 24 (58.5%) patients initially treated with 70 mg erenumab, after 2-6 months (median: 3 months (IQR: 2-6)), it was decided to increase the dose to 140 mg due to insufficient effect. In 12 (50%) of these patients, the effect was achieved after increasing the dose, and in 4 patients who did not respond to treatment, it was decided to switch from erenumab to fremanezumab. When comparing CM and EM groups, the initial dose was increased more often in patients with CM (14 (77.8%) vs. 10 (43.5%), p=0.027). Detailed information about erenumab dose changes and effect assessment is shown in Figure 3.

Treatment with erenumab was discontinued in a total of 10 (14.9%) patients, two after 3 months and eight after 6 months. The main reason for discontinuation was medication ineffectiveness or secondary loss of response. Adverse events such as constipation, weight gain, and hair loss led to the discontinuation of erenumab in only one patient (with concomitant observation of lack of efficacy). Fremanezumab was discontinued in a total of 3 (16.7%) patients, two after 3 months and one after 6 months; the main reasons for discontinuation were adverse events such as local allergic reactions/allergic dermatitis and hair loss; fremanezumab was not discontinued due to lack of efficacy. Assessing the overall incidence of adverse events, it was found that fremanezumab (22.2%) had a slightly higher incidence of adverse effects than erenumab (3%, p=0.017).

DISCUSSION

A recent study showed that the efficacy of erenumab treatment between CM and EM was similar, with slightly better results observed in the EM group. Similar results for erenumab treatment were reported by Schoenen et al. [10], a significant difference between EM and CM was observed only at 3 months, afterwards the difference disappeared (at 6, 9 and 12 months). However, there is currently growing evidence that outcome of treatment also depends on the selection of dose [5, 11]. Our study found that 58.5% of patients who started erenumab at 70 mg needed a dose increase, especially patients with CM. However, we were unable to assess the effect of drug dose on efficacy due to the small number of patients. Although at least 3 months after the initiation of erenumab for migraine prevention are recommended before the assessment of response [12], in our clinic the dose was sometimes changed after 2 months. Talbot et al. [13] obtained similar results in their study: of 98 subjects, 57% received a dose escalation after 2 months. However, according to different authors, 30-74.1% of patients require a dose increase [13–17]. Also, previous studies reported a higher efficacy of erenumab at a dose of 140 mg compared to 70 mg [18, 19]. The choice between erenumab 70 mg and 140 mg may be based on factors that indicate difficult-to-treat disease. These include patients in whom prior preventive treatment were unsuccessful and patients with acute medication overuse [20–22]. According to other researchers, erenumab 140 mg may be better for preventing disease progression by reducing the potential of conversion from EM to CM, for increasing the likelihood of reversion from CM to EM, and for increasing the probability of reversing acute medication overuse to non-overuse of acute medication [22, 23]. Erenumab 140 mg is the starting dose for some patients with difficult-to-treat disease, prior treatment failures, and for those most at risk of conversion from EM to CM [7].

Our study shows that when comparing the efficacy of fremanezumab between CM and EM, slightly better results were observed in the EM group, but there was no statistically significant difference between the groups. Goadsby et al. [24] found a lower efficacy of fremanezumab, but in our study, the effect was slightly better in the EM group. The precision of our results may have been influenced by a small number of subjects (n=18). When comparing the efficacy of erenumab and fremanezumab, a slightly better response was achieved in the fremanezumab group. A meta-analysis by Soni et al. [25] showed that fremanezumab is slightly more effective than erenumab in the treatment of CM, but no statistically significant difference was obtained in their study either.

When comparing the incidence of adverse events between fremanezumab and erenumab, a statistically significant difference was found, and fremanezumab discontinuation due to adverse events was more common. However, the literature shows that fremanezumab does not have a different rate of adverse reactions than placebo or erenumab [25, 26]. A study conducted in Japan and Korea [26] showed that fremanezumab was well tolerated and the incidence of adverse events, including injection site reactions, was similar to placebo (at least one adverse event occurred in 61.4% (n=232) of fremanezumab treated patients and 61.8% (n=118) of placebo treated patients). The discrepancy in our study may be due to the method used (retrospective data analysis), as patients who experienced minor side effects may not have reported this to their physician. Alternatively, the results can be explained by the fact that the decision to discontinue taking fremanezumab could have been made by the patient without an objective assessment of the severity of the side-effects and the benefit-risk ratio (in the study, fremanezumab treatment was stopped due to localized allergic reactions and hair loss).

The main limitations of our study are that the data were collected from medical records, a small sample size, especially in patients treated with fremanezumab. Also, patients were consulted by different doctors, so there may be different interpretations of the clinical effect, and due to frequent and heterogeneous dose changes (escalation and de-escalation), comparisons between 70 mg and 140 mg were not possible. The advantage of our study is its novelty; this is the first study assessing the effectiveness of anti-CGRP moncolonal antibodies in our clinic, although this is not the first study on this topic in Lithuania. Data of migraine treatment with erenumab from another Lithuanian headache center have already been published [27]. All the data collected will be useful in daily clinical practice, as anti-CGRP moncolonal antibodies have recently been introduced for migraine prevention.

CONCLUSIONS

1. Both anti-CGRP mAbs, erenumab and fremanezumab, are effective and equivalent in the treatment of chronic and episodic migraine.
2. The efficacy of anti-CGRP mAbs is not significantly affected by disease phenotype.
3. More than half of the patients who started treatment with erenumab 70 mg required dose escalation, especially in CM group.
4. Erenumab and fremanezumab are safe in adults, adverse reactions are rare but more common with fremanezumab.

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PROFILAKTINIO MIGRENOS GYDYMO MONOKLONINIAIS ANTIKŪNAIS PRIEŠ CGRP RETROSPEKTYVI ANALIZĖ, ATLIKTA LIETUVOS SVEIKATOS MOKSLŲ UNIVERSITETO LIGONINĖJE KAUNO KLINIKOSE

Santrauka

Įvadas. Migrena yra pirminis galvos skausmo sutrikimas, apibūdinamas pasikartojančiais galvos skausmo epizodais, kuriems dažnėjant pasireiškia lėtinė migrena (LM). Šiuo metu pasaulyje plačiai nagrinėjamas profilaktinis migrenos gydymas monokloniniais antikūnais prieš CGRP.

Tiriamieji ir tyrimo metodai. 85 pacientai, sergantys migrena, buvo įtraukti į retrospektyvinį tyrimą, atliktą 2019–2021 m. Rinkti ir analizuoti demografiniai bei klinikiniai ligos duomenys. Tiriamieji suskirstyti į grupes pagal migrenos eigą – LM ir epizodinę migreną (EM), bei pagal migrenos profilaktiniam gydymui skirtą vaistą – erenumabą arba fremanezumabą. Gydymo efektyvumas vertintas praėjus 3 ir 6 mėn. nuo gydymo pradžios. Geru atsaku laikytas galvos skausmo (GS) dienų skaičiaus sumažėjimas 50 %. Statistinė duomenų analizė atlikta naudojant SPSS Statistics 27.0 programą, ^{2} homogeniškumo, Fišerio, Stjudento t ir Mano-Vitnio kriterijus.

Rezultatai. Tarp 85 pacientų, sergančių migrena, buvo 75 moterys (88,2 %). EM diagnozuota 33 pacientams (38,8 %), LM – 52 (61,2 %). Po gydymo abiejose vaistų nuo CGRP grupėse GS dienų skaičius reikšmingai sumažėjo ($p < 0,001$). Atsakas į gydymą monokloniniais antikūnais buvo panašus tarp EM ir LM grupių. Kiek geresnis atsakas pasiektas gydant fremanezumabu nei erenumabu (83,3 % ir 73,1 % – po 3 mėn.; 83,3 % ir 65,7 % – po 6 mėn.), tačiau skirtumas nebuvo reikšmingas ($p = 0,541$; $p = 0,149$). 24 pacientams (58,5 %), kuriems pradžioje skirta 70 mg erenumabo, po 2–6 mėn. (mediana – 3 mėn. (IQR: 2–6)), nestebint pakankamo efekto, buvo nuspręsta padidinti erenumabo dozę iki 140 mg. Pradinė dozė didinta reikšmingai dažniau LM grupėje ($p = 0,027$).

Išvados. Erenumabas ir fremanezumabas yra vienodai efektyvūs ir lygiaverčiai gydant lėtinę bei epizodinę migreną. Pastebėta, kad daugiau nei pusei pacientų, gydytų 70 mg erenumabu, reikėjo didinti dozę, ypač pacientams, sergantiems LM.

Raktažodžiai: lėtinė, epizodinė migrena, erenumabas, fremanezumabas, gydymas.

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