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CRITICAL REVIEW OF AIMOVIG (ERENUMAB) FOR MIGRAINE

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ABSTRACT

Migraine is a common neurological disorder associated with recurrent moderate-to-severe headache episodes that considerably affect quality of life and daily activities. Existing preventive therapies are often associated with limited efficacy and poor patient compliance. The identification of calcitonin gene-related peptide (CGRP) as a key mediator in migraine pathophysiology has contributed to the development of targeted therapies such as erenumab (Aimovig), a monoclonal antibody that blocks CGRP receptors. This review critically evaluates the research article by Goadsby et al. on the efficacy and safety of erenumab for episodic migraine prevention. The reviewed study was a multicentre, randomized, double-blind, placebo-controlled phase III clinical trial involving patients with episodic migraine. Participants received placebo, erenumab 70 mg, or erenumab 140 mg subcutaneously once every four weeks for six months. The study demonstrated significant reductions in monthly migraine days, decreased use of acute migraine medications, and improvement in physical functioning among patients treated with erenumab compared to placebo. The 140 mg dose showed comparatively greater effectiveness. Safety evaluation revealed that adverse events and treatment discontinuation rates were similar across all groups, indicating good tolerability of the drug. The methodological strength of the study, including adequate randomization and blinding, enhanced the reliability of the findings. However, limitations such as short study duration and exclusion of treatment-resistant patients were noted. Overall, erenumab appears to be an effective and safe preventive treatment option for episodic migraine.

KEYWORDS: Migraine, Erenumab, Aimovig, CGRP, Episodic migraine, Monoclonal antibody, Preventive therapy, Clinical trial.

INTRODUCTION

Migraine is an increasingly prevalent neurological condition, and can be defined as an episodic, predominantly unilateral headache, moderate-to-severe in intensity and is often presented with additional features like nausea, sensitivity to light, sound and movement (Ruschel & Jesus, 2019; Amiri, 2022). Migraine is classified into multiple subtypes including the one with aura, without aura and chronic migraine (International Headache Society, 2018). More than one billion people across the globe are being affected by migraine every year, with an estimated prevalence of above 12% (Safiri et al., 2021). The prevalence of migraine is three times higher in females than males i.e, 18% vs 6% (Lipton et al., 2007) Migraine incurs disability, affects day-to-day activities of the patient and is the second most common neurological condition causing disability. In 2016, it accounted for about one- fifth of the disability-adjusted life years lost (Feigin et al., 2019). There is no exact cause for migraine, but the acute episodes are triggered by various factors that vary from patient-to-patient. This disease is assumed to associated with a strong genetic component which is responsible for its inheritance pattern, but the loci responsible for this still remain uncertain (de Vries et al., 2016). Treatment of acute episodes of migraine is based on symptoms and includes anti-emetics, analgesics such as paracetamol and other non-steroidal anti-inflammatory agents and serotonin receptor antagonists (triptans) (Schwedt & Garza, 2022). For prevention of migraine episodes, drugs like propranolol, topiramate, valproate and amitriptyline are used despite the fact that these drugs are not completely effective as they were not designed to target the physiological cause of migraine (Zobdeh et al., 2021).

Identification of Calcitonin Gene-Related Peptide

(CGRP) and its role in the pathophysiology of migraine, through activation of trigemino-vascular system has been a breakthrough in the development of drug targets for migraine (Edvinsson, 2017). This was followed by development of targeted therapy i.e., anti-CGRP agents (King et al., 2019). Erenumab, marketed under the brand name Aimovig is a monoclonal antibody that blocks the CGRP receptor and is the first approved monoclonal drug for preventing acute episodes of migraine (Edvinsson, 2019; FDA News release, 2018). This report is a critical review of a research article titled ***"A Controlled Trial of Erenumab for Episodic Migraine"*** published by Goadsby et al., 2017. This report analyses multiple aspects of the article including its methodological design, findings from the research and their interpretations, along with a critique on ethical aspects.

Description of the article

The researchers Goadsby and his colleagues designed a multicentred, randomised, double- blind, placebo-controlled phase 3 trial. The main aim of the study was to evaluate safety and efficacy of enerumab as preventive therapy in patients diagnosed with episodic migraine. This study is based on the hypothesis that blocking CGRP-receptors prevents the acute episodes of migraine, and enerumab is a CGRP-receptor antagonist that could exhibit preventive benefits in migraine. The first statement of the hypothesis is backed by multiple studies in which blockage of CGRP-receptors by newer molecules was used as a strategy to treat migraine head ache. These molecules are as follows: BIBN 4096 BS (Olesen et al., 2004), MK-0974 (telcagepant) (Ho et al., 2008), BI 44370 TA (Diener et al., 2010), MK-3207 (Hewitt et al., 2011), BMS-327711 (Marcus et al., 2013) and ubrogepant (Voss et al., 2016). These are low molecular weight CGRP-blockers, oral agents that have showed promising benefits for acute migraine attacks in their corresponding phase II trials. The second part of hypothesis, i.e., the efficacy of erenumab as preventive therapy is supported by a phase II study by Sun et al., 2016. Sun 2016 in their study evaluated enerumab (then known as AMG 334) at different doses of 7 mg, 21 mg and 70 mg administered subcutaneously for its benefits as migraine preventive therapy in a randomised double-blind trial. The results of this phase II study suggested that erenumab showed promising benefits at a minimum dose of 70 mg. Therefore, the researchers of the present study evaluated erenumab at doses 70 mg and its double strength 140 mg. For this purpose, Goadsby, 2017 have chosen a randomised controlled trial, where the outcomes of erenumab are compared against a matching placebo. Randomised controlled trials are considered as the gold standard for establishing causal relationship of the research outcomes with the intervention used (Kabisch et al., 2011). In addition to this, double-blinding helps in prevention of deception in the study and decreases the risk of bias through the investigator (researcher bias) (Misra, 2012).

The researchers included patients aged between 18 and 65 years and have a clinical diagnosis of episodic migraine. They have defined migraine according to third edition of the international classification of head ache disorders. And, patients were eligible for the study only if they had migraine for 4-15 days in a month and provided a written informed consent. Informed consent is a basic research document required when studies involve human participants (Musmade etal., 2013). The authors also stated that they have obtained approval from ethics committees at each study centre. This suggests that the researchers fulfilled the ethical considerations required for the clinical research.

Summary of the findings

In this study, a total of 955 patients were randomised in a 1:1:1 ratio to placebo group (319 patients), erenumab 70 mg group (317 patients) and erenumab 140 mg group (319 patients). All the patients were administered with their respective intervention subcutaneously once in every four weeks untul week 20. The researchers evaluated and baseline characteristics (both clinical and demographical factors) among the three groups and observed that they were similar and balanced. Similar baseline characteristics are an indication for an appropriate randomisation and also helps in distinguishing the differences in study outcomes which are attributable to the specific study groups (de Boer et al., 2015).

All the patients were followed up until 6 months from the day of first dose. To evaluate the outcomes, the researchers asked the patients to complete an electronic dairy that consists of detailed information about episodes of migraine, severity, duration, details of onset and remission and additional symptoms. They were also asked to complete a self-administered questionnaire called Migraine Physical Function Impact Diary (MPFID) which measures patient functioning in 24 hours. Using electronic dairies is a smart way of collecting data. This reduces the hustle of data collection, organisation and entry into statistical software which is needed in manual diaries. Electronic data collections allow easy organisation and analysis of data and is also environmentally friendly.

The researchers measured the study outcomes based on the clinical features and patient- reported features in the last three months of the six months follow-up. The outcomes of the studies mainly included number of days with migraine in a month, number of patients with more than 50% decrease in migraine days in a month, number of days in which medications are needed for acute migraine pain along with the MPFID scores. These efficacy and safety outcomes were evaluated in patients belonging to erenumab 70 mg and 140 groups and were compared to those receiving placebo. The summary of results regarding the efficacy outcomes are depicted in Figure 1. Figure 1 is a directly taken from the research article originally published by Goadsby, 2017.

Table 2. Clinical Responses and Patient-Reported Outcomes over the Final 3 Months of the Double-Blind Treatment Phase (Months 4, 5, and 6).*

Outcome	Placebo (N=316)	Erenumab, 70 mg (N=312)†	Erenumab, 140 mg (N=318)†
Migraine days per month			
Change from baseline	−1.8±0.2	−3.2±0.2	−3.7±0.2
Difference vs. placebo (95% CI)	—	−1.4 (−1.9 to −0.9)	−1.9 (−2.3 to −1.4)
≥50% Reduction from baseline in migraine days per month			
No. of patients (%)	84 (26.6)	135 (43.3)	159 (50.0)
Odds ratio (95% CI)	—	2.13 (1.52 to 2.98)	2.81 (2.01 to 3.94)
Days of use of acute migraine–specific medication per month			
Change from baseline	−0.2±0.1	−1.1±0.1	−1.6±0.1
Difference vs. placebo (95% CI)	—	−0.9 (−1.2 to −0.6)	−1.4 (−1.7 to −1.1)
Monthly MPFID everyday-activities score			
Change from baseline	−3.3±0.4	−5.5±0.4	−5.9±0.4
Difference vs. placebo (95% CI)	—	−2.2 (−3.3 to −1.2)	−2.6 (−3.6 to −1.5)
Monthly MPFID physical-impairment score			
Change from baseline	−2.4±0.4	−4.2±0.4	−4.8±0.4
Difference vs. placebo (95% CI)	—	−1.9 (−3.0 to −0.8)	−2.4 (−3.5 to −1.4)

Figure 1 Efficacy outcomes of erenumab 70 mg and 140 mg compared with placebo. (Source: This figure is a direct excerpt from the original publication by Goadsby et al., 2017).

From the table, it can be observed that change in number of days of migraine per month was significantly reduced in all the three group. Placebo group showed an average reduction by 1.8 days while erenumab groups showed reduction of migraine days by 3.2 and 3.7 days with 70 mg and 140 mg respectively. This suggests that erenumab decreases the frequency of migraine by two times when compared to placebo. When doses of erenumab are compared, 140 mg is found to be more effective in reducing the frequency of migraine episodes. When the number of patients with more than 50% reduction in migraine days is compared, placebo group had 26.6% patients, erenumab 70 mg group had 43.3% patients and erenumab 140 mg group had 50% of the patients. This suggests that half of the patients in the 140 mg group has seen significant reduction of more than 50% in terms of frequency acute episodes of migraine. The days where in patients required medication of acute migraine episodes was also favourable towards erenumab groups. Patients in placebo group showed negligible difference from baseline in terms of this outcome. That means, erenumab reduced the need of medications for acute migraine episodes.

The MPFID score was divided in to two categories: everyday activities and physical impairment. Both the doses of erenumab showed significant reductions in terms of migraine causing physical impairment and affecting everyday activities when compared to placebo. This suggests that erenumab significantly reduces the disability incurred by migraine on day-to-day activities and improves the quality of life. All these outcomes suggest that erenumab at a dose of 140 mg is effective as a preventive treatment in patients with episodic migraine.

The safety of this new drug was evaluated by measuring the incidence of adverse events in placebo group, erenumab 70 mg group and erenumab 140 mg group. The results from the safety analysis are displayed in figure 2. Figure 2 is directly adapted from the article originally published by the authors.

Table 3. Adverse Events Reported during the Double-Blind Treatment Phase.*

Event	Placebo (N=319)	Erenumab, 70 mg (N=314)	Erenumab, 140 mg (N=319)
	number of patients (percent)		
Adverse event	201 (63.0)	180 (57.3)	177 (55.5)
Adverse events reported by ≥2% of patients in any trial group			
Nasopharyngitis	32 (10.0)	31 (9.9)	35 (11.0)
Upper respiratory tract infection	18 (5.6)	21 (6.7)	15 (4.7)
Sinusitis	7 (2.2)	7 (2.2)	11 (3.4)
Constipation	4 (1.3)	5 (1.6)	11 (3.4)
Arthralgia	6 (1.9)	7 (2.2)	7 (2.2)
Fatigue	8 (2.5)	6 (1.9)	7 (2.2)
Nausea	6 (1.9)	7 (2.2)	6 (1.9)
Influenza	6 (1.9)	4 (1.3)	8 (2.5)
Urinary tract infection	7 (2.2)	5 (1.6)	7 (2.2)
Back pain	7 (2.2)	6 (1.9)	6 (1.9)
Injection-site pain	1 (0.3)	10 (3.2)	1 (0.3)
Migraine	10 (3.1)	4 (1.3)	3 (0.9)
Hypertension	8 (2.5)	5 (1.6)	0
Adverse event leading to discontinuation of trial regimen	8 (2.5)	7 (2.2)	7 (2.2)
Serious adverse event†	7 (2.2)	8 (2.5)	6 (1.9)

Figure 2: Safety outcomes of erenumab 70 mg and 140 mg compared with placebo. (Soruce: This figure is a direct excerpt from the original publicaiton by Goadsby et al., 2017).

From the figure 2, it can be observed that the incidence of adverse events is highest in the placebo group, followed by erenumab 70 mg group and then erenumab 140 mg group (63% vs 57.3% vs 55.5%). The adverse events were recorded from day 1 until the end of follow-up i.e, 6 months. The incidence of serious adverse events was also lesser in erenumab 140 group when compared with the other two groups (2.2% in placebo, 2.5% in 70 mg group and 1.9% in 140 mg group). The events resulting in treatment discontinuation was similar in all the three groups (2.5% vs 2.2% vs 2.2%). The results from safety profile suggests that erenumab 140 is safe and does not have any increased risk of adverse events when compared to placebo.

The results of the study by Goadsby, 2017 were similar to other studies that evaluated this same drug in patients with other types of migraine. Tepper et al., 2017 evaluated erenumab and suggested it is safe and effective in chronic migraine patients. Later on, Ashina et al., 2021 conducted a 5 year study and suggested that erenumab is safe and effective in long-term use.

Strengths and Limitations

There are more strengths than limitations for the present study. The researchers have designed a sophisticated research project, by adopting a randomised controlled design which is the best clinical research design. The sample size was quite high enough to estimate differences among the three study groups. The researchers state that the only limitation of the research is that they have excluded patients who had no response with previous medications. By excluding these patients, the researchers failed to show whether erenumab was effective in patients with treatment resistant migraine. The other limitation of the study is the duration. In six months, long term effects could not be estimated.

CONCLUSION

From all the aspects putforth from the research study by Goadsby et al., 2017, it can be concluded that blocking CGRP receptor can prevent migraine episodes. Erenumab, which is an anti-CGRP monoclonal antibody is effective and safe in decreasing the frequency of migraine episodes. From the stringent methodological design of this study, it can be stated that the results carry very lower risk of bias and can be generalisable to population with episodic migraine. This study helps in physicians making a decision towards prescribing enerumab as prophylaxis for migraine. Further studies might focus on evaluating other agents that directly target the pathological pathways of migraine.

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