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Original

Effectiveness of migraine prophylaxis with rational polytherapy and patient satisfaction using the Likert scale: a real-world study

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Abstract

Background
Chronic migraine is a debilitating neurological condition that affects more women than men and impacts their most productive years of life. Preventive treatment in real world remains a challenge, as the response to treatment is often poor.

Objectives
Our objective was to demonstrate the effectiveness of prophylactic treatment for chronic migraine using a rational combination of "traditional" drugs and to highlight the degree of patient satisfaction.

Methods
This was an observational, retrospective, uncontrolled, and descriptive study. A non-random convenience sample of 100 consecutive women diagnosed with chronic migraine and treated with rational polytherapy.

Results
One hundred women diagnosed with chronic migraine, with a mean age of 41±11.9 years and ages ranging from 19 to 68 years, were treated with rational polytherapy. At least two prior prophylactic treatments were prescribed to 68% of patients. The mean frequency of headache at baseline was 23.7±4.3 days per month. After 4 months of treatment, there was a reduction in the number of headache days per month to 5.3±5.1 ($p<0.001$). There was a reduction in the number of headache days >50% in 97% of patients. A high degree of satisfaction with the treatment was observed in 69% of patients.

Conclusions
The rational combination of traditional medications for the prophylaxis of chronic migraine has proven effective, causing a reduction in the number of headache days per month and generating satisfaction among treated patients. Real life practice in tertiary care with patient centered medicine may result in more outcomes that are robust for chronic migraine patients.

Keywords
Chronic migraine
Prophylactic treatment
Rational polytherapy
Satisfaction level

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Introduction

Chronic migraine is a debilitating neurological condition affecting approximately 1.4 to 2.2% of the global population, generating a substantial impact on both individuals' lives and the economy (1). It affects more women than men (1.7 to 4% vs. 0.6 to 7%), with a peak incidence in middle age, impacting their most productive years of life (2).

Treating chronic migraine is challenging because the response to treatment is often poor, especially "in the real world and when performed by doctors who are not headache experts". Patients with chronic migraine tend to be less satisfied with the therapeutic response (38%) compared to those who suffer from episodic migraine (66%) (3). The difficulties in treating chronic migraine stem from the numerous strategies that must be adopted, such as modifying risk factors, identifying triggers, managing comorbidities, and using treatments that prevent headache attacks (2,4,5).

Patients with chronic migraine need effective preventive treatment that reduces the frequency and severity of headache attacks (2). The most effective treatments for chronic migraine, and those recommended by current consensus, are onabotulinumtoxinA, topiramate (6), and monoclonal antibodies that act on CGRP (7,8).

However, clinically challenging cases of chronic migraine may benefit from combination therapy with medications recommended for episodic migraine, which have good safety, tolerability, and efficacy (9). The aim of this study is to demonstrate the effectiveness of prophylactic treatment for chronic migraine using a rational combination of "traditional" drugs, considering emerging therapeutic strategies for the treatment of chronic migraine, as well as highlighting the degree of patient satisfaction.

Methods

Study design and patients

This was an observational, retrospective, uncontrolled, and descriptive study. The study population consisted of a non-random, convenience sample of 100 consecutive women diagnosed with chronic migraine according to the ICHD-3 criteria. The patients were treated at a tertiary headache center by a neurologist with expertise in headache treatment (CAB), who prescribed rational polytherapy. Data for this study were collected from January 2018 to December 2021.

Inclusion and exclusion criteria

This study included female patients over 18 years of age, diagnosed with chronic migraine, according to the ICHD-3 criteria (10), presenting ≥15 days of headache per month resulting in functional disability in the last three months, and agree to use rational polytherapy as prophylaxis treatment for migraine. Patients diagnosed with migraine concomitantly with another primary headache, diagnosed with any secondary headache, having undergone treatment with botulinum toxin or monoclonal antibodies in the last six months, with uncontrolled arterial hypertension, cardiomyopathy and pregnant or not using a reliable contraceptive method women were excluded from the study.

Data collection

During the initial consultation, patients underwent a detailed medical history regarding the clinical characteristics of their headache, a neurological examination, and, when necessary, neuroimaging studies. All patients received prophylactic treatment and a headache diary to complete, which included headache characteristics and detailed information on the use of symptomatic medications. Furthermore, they were informed of the need for adherence to treatment for its success. If additional tests were required, treatment was initiated after the test results were delivered.

The choice of "rational" treatment was performed as suggested by Dodick and Silberstein (11) and the patients' profile. The medications were chosen according to patient profiles, such as drowsiness or insomnia, tendency towards hypotension or hypertension, dopaminergic profile or not, weight gain or loss, etc.

Rational drug combinations were made using drugs with actions on different events underlying the pathophysiology of migraine, generally two or three drugs from the following groups: a) anti-epileptic/neuromodulator (divalproate, topiramate or gabapentin); b) anti-serotonergics (amitriptyline, nortriptyline, venlafaxine or mirtazapine); c) dopaminergic blocker (chlorpromazine or quetiapine); d) beta-adrenergic blocker (propranolol or atenolol); and e) calcium channel blocker (flunarizine) (Table 1).

Table 1. Rational combination of traditional drugs in the prophylactic treatment of chronic migraine

Drug combination
Sodium divalproate (500-1000 mg/day) + amitriptyline (12.5-37.5 mg/day) + chlorpromazine (5-25 mg/day)
Sodium divalproate (500-1000 mg/day) + amitriptyline (12.5-37.5 mg/day) + quetiapine (12.5-50 mg/day)
Sodium divalproate (500-1000 mg/day) + nortriptyline (25-50 mg/day) + chlorpromazine (5-25 mg/day)
Sodium divalproate (500-1000 mg/day) + nortriptyline (25-50 mg/day) + quetiapine (12.5-50 mg/day)
Sodium divalproate (500-1000 mg/day) + venlafaxine (75-150 mg/day) + chlorpromazine (5-25 mg/day)
Sodium divalproate (500-1000 mg/day) + venlafaxine (75-150 mg/day) + quetiapine (12.5-50 mg/day)
Sodium divalproate (500-1000 mg/day) + mirtazapine (15-45 mg/day) + chlorpromazine (5-25 mg/day)
Sodium divalproate (500-1000 mg/day) + mirtazapine (15-45 mg/day) + quetiapine (12.5-50 mg/day)
Sodium divalproate (500-1000 mg/day) + propranolol (60-80 mg/day)
Sodium divalproate (500-1000 mg/day) + atenolol (25-50 mg/day)
Topiramate (75-125 mg/day) + amitriptyline (12.5-37.5 mg/day) + chlorpromazine (5-25 mg/day)
Topiramate (75-125 mg/day) + amitriptyline (12.5-37.5 mg/day) + quetiapine (12.5-50 mg/day)
Topiramate (75-125 mg/day) + nortriptyline (25-50 mg/day) + chlorpromazine (5-25 mg/day)
Topiramate (75-125 mg/day) + nortriptyline (25-50 mg/day) + quetiapine (12.5-50 mg/day)
Topiramate (75-125 mg/day) + mirtazapine (15-45 mg/day) + chlorpromazine (5-25 mg/day)
Topiramate (75-125 mg/day) + mirtazapine (15-45 mg/day) + quetiapine (12.5-50 mg/day)
Topiramate (75-125 mg/day) + venlafaxine (75-150 mg/day) + chlorpromazine (5-25 mg/day)
Topiramate (75-125 mg/day) + venlafaxine (75-150 mg/day) + quetiapine (12.5-50 mg/day)
Gabapentin (600-900 mg/day) + amitriptyline (12.5-37.5 mg/day) + chlorpromazine (5-25 mg/day)
Gabapentin (600-900 mg/day) + amitriptyline (12.5-37.5 mg/day) + quetiapine (12.5-50 mg/day)
Gabapentin (600-900 mg/day) + nortriptyline (25-50 mg/day) + chlorpromazine (5-25 mg/day)
Gabapentin (600-900 mg/day) + nortriptyline (25-50 mg/day) + quetiapine (12.5-50 mg/day)
Gabapentin (600-900 mg/day) + mirtazapine (15-45 mg/day) + chlorpromazine (5-25 mg/day)
Gabapentin (600-900 mg/day) + mirtazapine (15-45 mg/day) + quetiapine (12.5-50 mg/day)
Gabapentin (600-900 mg/day) + venlafaxine (75-150 mg/day) + chlorpromazine (5-25 mg/day)
Gabapentin (600-900 mg/day) + venlafaxine (75-150 mg/day) + quetiapine (12.5-50 mg/day)
Amitriptyline (12.5 – 37.5 mg/day) + propranolol (60-80 mg/day) + flunarizine (5 mg/day)
Amitriptyline (12.5 – 37.5 mg/day) + Atenolol (25-50 mg/day) + Flunarizine (5 mg/day)
Nortriptyline (25-50 mg/day) + propranolol (60-80 mg/day) + flunarizine (5 mg/day)
Nortriptyline (25-50 mg/day) + atenolol (25-50 mg/day) + flunarizine (5 mg/day)
Amitriptyline (12.5 – 37.5 mg/day) + flunarizine (5 mg/day)

Initial treatment consisted of a combination of two or three drugs (Table 1), with low doses and progressive increases when necessary. After 30 days of treatment, the patients were reassessed for possible medication adjustments, if necessary. Two further assessments were conducted at 60 days and 90 days. After four months, all patients determined the therapeutic efficacy through the application of a satisfaction scale (12). Patients who did not return within the specified timeframe were contacted by telephone three days later and asked to submit their headache diary and their level of satisfaction with the treatment.

In determining the degree of satisfaction with rational polytherapy, the Likert scale developed by psychologist and sociologist Rensis Likert (13) in 1932 was used, which uses statistical and psychological principles to improve data collection and feedback analysis in research. Patients described their level of satisfaction, according to their perception of improvement, using colloquial terms. Everyone answered the following question: "How satisfied are you / how much have you improved with the prophylactic migraine treatment?" Five verbal descriptors were developed: "no improvement (continues to have pain)", "slight improvement (improved a little)", "moderate improvement (improved reasonably)", "marked improvement (very few pain)" and "excellent (no pain at all)". Patients chose a single option, which were assigned scores from 1 to 5 (Table 2).

Table 2. Verbal descriptors of satisfaction level and their respective scores

Level of satisfaction	Scores
No improvement (pain continues)	1
Slight improvement (improved little)	2
Moderate improvement (Improved considerably)	3
Marked improvement (very few pain)	4
Excellent (no pain at all)	5

Statistical analysis

The Statistical Package for the Social Sciences (SPSS®) version 18.2.2 was used for statistical analysis. Quantitative variables were expressed as mean, standard deviation, and minimum and maximum values, while qualitative variables were expressed as absolute and relative frequencies with 95% confidence intervals. The chi-square test with Yates correction and the t-test were used for the difference of means of paired samples. All tests will be performed at a significance level of 0.05 for rejection of the null hypothesis.

Ethical aspects

The research was submitted for approval to a Research Ethics Committee Involving Human Subjects. The data were collected from access to the archived medical records of patients at the study site, and a Data Use Commitment Agreement was presented, in compliance with Resolution 738/2024, which governs the use of databases for scientific research involving human beings.

Results

One hundred women were diagnosed with chronic migraine, with a mean age of 41±11.9 years. The age ranged from 19 to 68 years. All patients experienced >15 days of headache per month, with an average of 23.7±4.3 days per month. The number of days with severe pain occurred 15.1 ± 5.1 days per month. The clinical and epidemiological characteristics of women with migraine are summarized in Table 3.

We found that 68% of patients had already undergone at least two previous prophylactic treatments (Figure 1).

Table 3. Characterization of headache

Characteristics of pain	
Age at diagnosis (years; SD; variation)	41±11.9 (19–68)
Frequency of headache (days per month; SD; variation)	23.7±4.3 (16–30)
Frequency of severe pain (days per month; SD; variation)	15.1±5.1 (6–27)

SD: standard deviation.

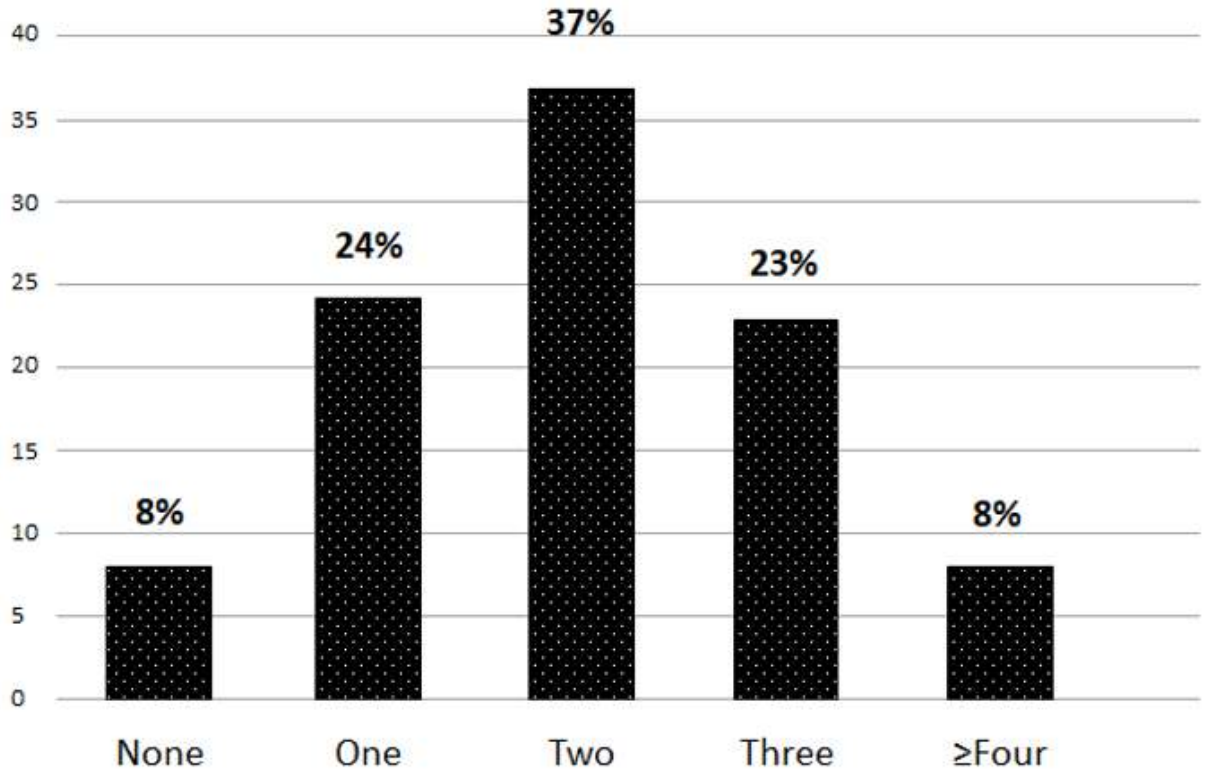

Figure 1. Number of previous prophylactic treatments.

The mean monthly frequency of headache at baseline was 23.7 ± 4.3 (95% CI 22.9–24.5) days per month. After four months of treatment, there was a reduction in the number of headache days per month to 5.3±5.1 (95% CI 4.3–6.3) (p<0.001) (Table 4).

Table 4. Comparison between baseline and after 4 months of prophylactic migraine treatment with rational polytherapy

Variables	**Comparison groups**		***p* value**
	At baseline	**After 4 months**	
Frequency of headache attacks (days per month)			<0.0001
Average	23.7	5.3	
standard deviation	4.3	5.1	
95% confidence interval	22.9-24.5	4.3-6.3	

It was found that, after the fourth month of treatment, 97% of patients had a reduction in the number of days with pain greater than 50% compared to baseline. Patients demonstrated a high degree of satisfaction with the effectiveness of migraine prophylaxis, and 69% of them described being "with very few pain or pain-free" (Figure 2).

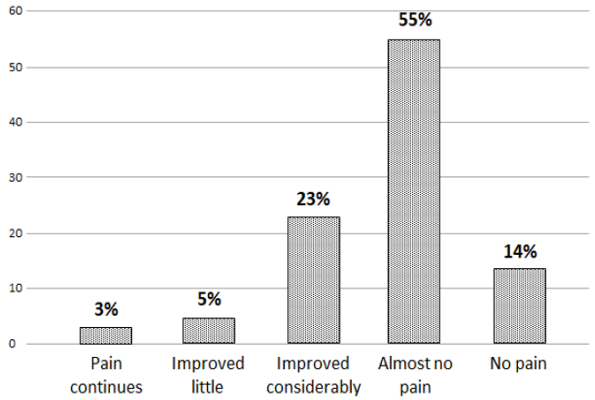

Figure 2. Degree of satisfaction of patients treated with rational polytherapy, according to the Likert scale.

Discussion

In our study, the sample consisted exclusively of women because they represent the majority in a tertiary center, to avoid possible differences in response between genders, and because they are more affected by migraine, whose headache attacks have a longer duration and intensity, with an increased risk of recurrence and causing significant disability. Furthermore, women have more comorbidity and are more likely to develop the chronic form of the disease (14). Although one hundred patients were followed for a period of four months, no patient dropped out of the study during that time. This was due to the study design, which allowed researchers to contact all patients.

Patients with chronic migraine frequently report having used various prophylactic treatments previously (15), which were discontinued due to treatment failure or adverse events (16). Despite the existence of several medications used for the preventive treatment of chronic migraine, there is still little information on practical evidence regarding their effectiveness (17). Typically, migraine patients report treatment failures after an average of 2-3 previous treatments, as we found in our study. We found that 68% of our patients had already undergone prior prophylaxis; this finding suggests that these were patients who were usually more resistant to treatment, which would imply further evidence of the effectiveness of the therapeutic strategy used in the present study (Figure 1). Failures in preventive treatment are often a cause for concern due to the increased number of headache days per month, overuse of analgesics, and greater disease severity (18).

Many patients do not respond to monotherapy as a preventive treatment for chronic migraine. Polytherapy can exert additive or synergistic effects when traditional drugs are used in combination (19). Real-world data on the combination of these medications is still scarce. The trend is for this combination to be made with traditional drugs, because despite the advent of monoclonal antibodies, even in developed countries, they have not been the most widely used worldwide, mainly due to economic constraints (20). This study corroborates a previous study on the effectiveness of traditional treatments (21) and shows that traditional medicines are valuable tools in the prevention of chronic migraine and should continue to be a therapeutic option, especially in resource-limited regions.

There is evidence that the rational combination of drugs increases the effectiveness of prophylactic migraine treatment, characterized by a 50% decrease in headache days per month or migraine days per month (22). There is no single pathophysiological mechanism in migraine to explain the headache attacks and associated symptoms, such as cortical spreading depression, the trigeminovascular system, neurogenic inflammation, vasodilation, and genetic vulnerability. It appears that the fundamental physiological disturbance is central neuronal hyperexcitability, involving peripheral trigeminovascular or brainstem pathways, or both. Several factors can increase or decrease neuronal excitability, constituting the threshold for triggering headache attacks (23,24). Due to this multiplicity of pathways and pathophysiological processes, the use of drug combinations must be logical.

The combination of drugs used in the prevention of chronic migraine is a useful and frequent strategy (11), as it manages to target the various and complex factors involved in this condition, such as neuronal hyperexcitability, neurogenic inflammation, calcium channel dysregulation, and low serotonin levels (25). The rational use of multiple medications has demonstrated effectiveness in the treatment of chronic migraine compared to the use of a single medication (22,26). Our patients used a combination of drugs and experienced a reduction in the number of headache days per month after 4 months of treatment (27.7 days vs. 5.3 days) (Table 4), possibly greater than other studies (15), as well as 97% of patients achieving a greater than 50% reduction in headache days. The high success rate is possibly due to patient selection, the fact that it is a non-university tertiary center, the type of treatment, and perhaps the doctor's expertise, or all of these factors.

There is another practical and realistic parameter that has gained interest, which is the degree of patient satisfaction, and it is associated with improved functional outcomes (27). Many studies have evaluated patient satisfaction with treatment for migraine (28). In this study, patients demonstrated a high degree of satisfaction with rational polytherapy in chronic migraine, confirming that headache diaries often do not reflect the patient's reality.

There are possible explanations for why our findings were more robust than in other studies. In double-blind, randomized clinical trials, emphasis is placed on avoiding factors that could influence the results, such as a more impersonal doctor-patient relationship, the expectation of ingesting a placebo, lack of trust in the professional, etc. However, it has long been known that the doctor-patient relationship, involving empathy, understanding, and trust in the prescriber, are cornerstones for increased effectiveness, as is the expectation of receiving treatment from a renowned expert, etc.

There is no doubt that the scientific method has brought advances to medicine; however, it is possible that the factors listed above and the emphasis on patient-centered medicine and the patient-physician relationship could lead to better results than those of the very well-designed clinical trials presented to us every day. Furthermore, the robustness of the findings suggests that, despite entering a new era in migraine prophylaxis, traditional drugs represent a useful alternative and should not be neglected.

Study limitations

This study had some limitations, such as the retrospective design; the absence of a double-blind, randomized, placebo-controlled trial; the potential for selection bias due to the convenience sample from a single center; the relatively small sample size; a follow-up period of only four months; and the scarcity of previous clinical studies or systematic reviews. However, we believe that the aforementioned limitations did not interfere with the generalizability of the results. On the other hand, the same neurologist was responsible for the initial assessment and the reassessment after four months, and no patient dropped out, which is a strong point of the study.

Conclusion

The rational combination of traditional drugs for the prophylaxis of chronic migraine has proven to be very effective, promoting a reduction in the number of headache days per month and causing enormous satisfaction among treated patients. This approach may be particularly useful in situations of resource scarcity.

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