



Primary care intervention for migraine patients

Dr. Patricio Jaramillo Guerrero

Professor of Medicine at the Universidad Regional Autónoma de los Andes (UNIANDES).
Email: ua.patriciojaramillo@uniandes.edu.ec, Orcid: <https://orcid.org/0000-0003-4612-7501>

Dr. Neyda Hernández Bandera

Professor of Medicine at the Universidad Regional Autónoma de los Andes (UNIANDES).
Email: ua.neydahernandez@uniandes.edu.ec, Orcid: <https://orcid.org/0000-0001-9015-4924>

Dr. Alvaro Paúl Moina Veloz

Professor of Medicine at the Universidad Regional Autónoma de los Andes (UNIANDES Ambato).
Email: ua.alvaromoina@uniandes.edu.ec, <https://orcid.org/0000-0002-8050-8562>

2254

Abstract

Introduction: There is evidence for a psychological intervention that appears to be effective for the management of migraine

Objective: to evaluate the effectiveness of an educational intervention in primary care for migraine management.

Methods: A parallel randomized controlled study was conducted on 116 patients from five primary care centers.

Results: PEDM scores for all five questions decreased by at least 50% in 68.9% (n = 37) of patients in the intervention group.

Conclusions: the intervention was for managing migraine, as it reduced the number of days lost due to the condition and decreased the pain intensity.

Keywords: migraine, intervention, primary care, psychology source: DeCS

Resumen

Introducción: Existe evidencia sobre una intervención psicológica que parece ser efectiva para el manejo de la migraña

Objetivo: evaluar la efectividad de una intervención educativa en la atención primaria para el manejo de la migraña

Método: Se realizó un estudio controlado aleatorizado paralelo en 116 pacientes de cinco centros de atención primaria

Resultados: Las puntuaciones PEDM de las cinco preguntas disminuyeron al menos un 50 % en el 68,9 % (n = 37) de los pacientes del grupo de intervención

Conclusiones: la intervención fue para el manejo de la migraña, ya que redujo el número de días perdidos por la condición y disminuyó la intensidad del dolor.

Palabras clave: migraña, intervención, atención primaria, psicología fuente: DeCS

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Introduction

Migraine is the sixth leading cause of days lived with disability worldwide. The level of migraine disability has increased in recent years, accounting for 1.3% of all life years lost to

disability worldwide. In addition, the condition has a negative impact on the quality of life of sufferers. In the U.S., the work or school productivity of people with migraine is reduced by at least 50%, as the prevalence of migraine is highest among people in the most productive



years (i.e., late adolescence through the fourth decade of life)^(1,2).

However, despite the numerous prevention and pharmacological treatment options available for migraine attacks, only 40% of patients are satisfied with their current treatment⁽³⁾. Regarding pharmacological treatment, it is important to note that 37% of patients who had used migraine medication in the past experienced adverse effects (drowsiness, tiredness, and difficulty thinking clearly).

The most widely accepted hypothesis on the origin of migraine attacks is based on a state of neuronal hyperexcitability leading to disseminated cortical depression and consequent sensitization of the trigeminovascular system, a prerequisite for the onset of pain⁽⁴⁾.

In recent decades there has been a radical change in how pain is understood. It is now considered that pain does not originate in peripheral nociceptors but in a network of brain regions called the pain neuromatrix, whose activation is necessary and sufficient to generate the perception of pain. Such activation can be triggered by the arrival of a nociceptive signal or by states of alertness due to an implicit perception of threat to the organism; although the threat may not be real and, therefore, could be modified by adjusting beliefs and behaviors that favor the occurrence of an attack. In addition, fear of pain is a factor closely related to headache severity ($R^2 = 6.1\%$; $P < 0.01$) and to pain-related disability ($R^2 = 4.5\%$; $P < 0.01$)⁽⁵⁾. The fear-avoidance model of chronic pain describes how people experiencing acute pain can become trapped in a vicious cycle of chronic disability and suffering.

An educational intervention based on pain neuroscience is effective in patients with chronic pain due to fibromyalgia, resulting in reduced pain and disability⁽⁶⁾. However, pain neuroscience education strategies have not been tested in patients with migraine. The scientific literature only collects evidence on a psychological intervention (including relaxation training and cognitive behavioral therapy) in patients with this condition, which seems effective for migraine management⁽⁷⁾. However, the evidence base still lacks quality. A recently published update on behavioral treatments for migraine concluded that these treatments appear to be as effective as a pharmacological treatment for migraine

prophylaxis. The observed effects are even more pronounced when combined pharmacological and behavioral treatments are applied⁽⁸⁾.

The study aimed to evaluate the effectiveness of a primary care-based group educational intervention in which patients were trained in current concepts of pain neuroscience as applied to migraine management in the condition, compared with usual medical care.

Method

A parallel randomized controlled study was conducted on 116 patients from five primary care centers in Ambato, diagnosed with migraines, who had at least one migraine attack per month despite treatment. Patients with mental illness and cognitive impairment were excluded, as these conditions could hinder the completion of follow-up. In addition, patients who could not attend all intervention sessions or had received training as part of the previous pilot study were also excluded. This study was approved by the Universidad Regional Autónoma de Los Andes (UNIANDES).

Patients were recruited between August 2018 and May 2020. All participants gave written informed consent prior to inclusion in the study. The study sample size was calculated, and it was estimated that a sample of 106 patients was required to detect a difference of at least 25 % (19 % vs. 44 %) in the rate of patients with a 50 % improvement in the Migraine Disability Evaluation Test (PEDM) between the comparison groups⁽⁹⁾.

The patients were divided into groups of 10 to 12 participants to attend five sessions, four given once a week for four weeks and the fifth, one month after the fourth session. Each session lasted 1 h and 45 min.

Patients in the control group received the usual clinical care consisting of periodic primary care appointments. The only difference between the two groups was the series of educational sessions provided to patients in the intervention group.

After recruitment, members of the research team in charge of the evaluations interviewed the patients. During the interviews, the following data were collected: demographic characteristics, beliefs about migraine, coping strategies for migraine attacks, PEDM questionnaire,



medication consumed, work time, emergency room attendance and limitation of daily activities due to migraine during the previous three months.

At 12 months after baseline, the study assessed the primary outcome measure, i.e., days lost to migraine-related disability measured by the PEDM questionnaire, i.e., the sum of responses to five specific questions on the level of disability (days lost or with reduced productivity at work/school, at home, and in leisure activities). A positive response to treatment was considered when the PEDM score decreased by at least 50% from baseline.

The main outcome measure (decrease $\geq 50\%$ in PEDM score compared with baseline measurements) was assessed with logistic regression. The authors constructed a crude model and a model adjusted for possible confounding variables, identified by bivariate analysis of each independent variable with the dependent variable. Results were expressed as odds ratio (OR) with corresponding 95% confidence intervals (95% CI). Only those variables that showed a statistically significant relationship with the dependent variable (decrease $\geq 50\%$ in PEDM score) were included in the adjusted model. The same model was used to analyze the secondary variables ($\geq 50\%$ decrease in pain intensity and frequency) and the number of analgesics taken in the previous three months ($P > 0.05$). The database and statistical processing of the data were performed and analyzed in the SPSS 26 statistical program (SPSS Inc., Chicago, IL, USA). Descriptive statistics were used for the collection, presentation and interpretation of the results.

Results

To evaluate the effectiveness of an educational group intervention for migraine management, 116 patients were studied between November 2018 and June 2020, of whom 115 completed the 12-month follow-up. One patient was lost due to the inability to contact him. Of the 115 patients who ultimately participated in the study, only 105 were evaluated for the primary outcome variable (decrease $\geq 50\%$ in PEDM score from baseline) because the other 10 patients scored zero on the PEDM questionnaire at baseline. Nevertheless, all

115 patients were included in the analysis of the other secondary outcomes.

Of the 116 patients included in the study, 57 (49.1%) were assigned to the intervention group and 59 (50.9%) to the control group. Overall, 95 were women (81.9%), and 95 (81.9%) were married or living with a partner. No significant differences were found in baseline characteristics between the groups ($p > 0.005$), except for taking preventive medication before the start of the study (nine patients (15.3%) in the control group vs. two patients (3.5%) in the intervention group, $p = 0.031$).

The PEDM scores of the five questions related to the level of disability decreased by at least 50% in 68.9% ($n = 37$) of the patients in the intervention group and 34.6% of those in the control group ($n = 18$), the difference being statistically significant ($P < 0.001$). In multivariate analysis, the difference between the groups remained significant (OR 4.225, 95% CI 1.826-9.777, $P = 0.001$). The ratio of response to non-response to treatment was 4.255 times higher in the intervention group than among patients in the control group. Interestingly, the intervention was more effective in patients living alone (Table 1).

Table 1. Effectiveness of group educational intervention in reducing PEDM score by $\geq 50\%$.

| 2.1 Univariate analysis | | | |
|-------------------------|--------------------------------------|------------------------------|-------|
| | $\geq 50\%$ reduction in PEDM score. | $< 50\%$ reducing PEDM score | p |
| intervention group | 69,8% | 30,2% | 0.000 |
| Control group | 34,6% | 65,4% | |

| 2.2 Multivariate analysis | | | | 95% CI for OR | |
|---------------------------|-------|-------|-------|---------------|----------|
| | B | p | OR | Un der | Superior |
| Intervention | 1.441 | 0.001 | 4.225 | 1.826 | 9.777 |



| | | | | | |
|--------------------------|----------------|-----------|-----------|-----------|------------|
| Separated/Single/Widowed | 1.2 43 | 0.0 34 | 3.4 66 | 1.0 98 | 10.9 34 |
| Constant | - 0,8 46 | 0.0 07 | 0.4 29 | - | - |

Source: statistical analysis, $p \leq 0.05$

Decreases of at least 50% in headache duration (in days) and intensity and in medication intake were evaluated, and significant differences were observed in all cases in favor of the intervention group ($P < 0.005$). The Hosmer-Lemeshow test indicated a good fit for all models ($P > 0.05$ in all cases).

Migraine had a greater life-limiting impact on patients in the control group than those in the intervention group, with a significant difference between the groups. Specifically, 32 patients in the control group (55.2 %) and only six patients in the intervention group (10.5 %) reported that migraine was quite, significantly limiting their daily activities at 12-month follow-up ($p < 0.001$).

Discussion

Advances in managing migraine are insufficient to improve the quality of life of migraine sufferers, and new therapeutic strategies are urgently needed to achieve better results. The purpose of this research was to explore such therapeutic alternatives for people with migraine. The present study aimed to evaluate the efficacy of an educational group intervention on pain neuroscience for the treatment and management of migraine. The intervention was more effective than usual care at 12-month follow-up in achieving a 50% or more significant decrease in PEDM score (OR 4.225; $P = 0.001$), pain intensity (OR 9.116; $P = 0.005$), and medication intake (OR 13.267; $P < 0.001$).

The results of this study are consistent with those obtained by other research groups. Rothrock et al.⁽¹⁰⁾ conducted a randomized controlled trial to evaluate the effectiveness of an educational intervention in patients diagnosed with migraine compared to standard care. Patients in the intervention group received written information on migraine biogenesis and treatment, along with three peer-to-peer sessions guided by migraine sufferers who had previously been educated on migraine biogenesis, prevention and treatment. The researchers observed a significant difference

in the change in PEDM scores from baseline. Specifically, scores decreased 24 points after 6 months of follow-up in the intervention group compared with 14 points in the control group patients. The decrease pattern was similar to that found in the present study (11.2 vs. 0.4).

As mentioned above, there has been some research on educational interventions for migraine management⁽¹¹⁾. However, no studies on educational interventions based on the neuroscience of pain were identified. However, these pain neuroscience educational interventions have been previously investigated for other conditions, such as fibromyalgia and lumbar radiculopathy, and were found to be effective^(12,13). Current evidence supports the use of neuroscience education for the reduction of chronic musculoskeletal pain through improved patient pain awareness, which, in turn, improves movement and minimizes the use of healthcare services.

The intervention tested in the study allowed to apply a conceptual framework developed by other authors for chronic low back pain, who proposed that migraine should be considered an abnormal threat perception that activates the body's defense system^(14,15). The underlying concept is that if migraine is considered an anomaly in brain perception, with a considerable component of cultural learning, rather than an inevitable consequence of a genetically hypersensitive brain, it is possible to modify that misperception through education.

In contrast to studies on group pain neuroscience educational interventions for fibromyalgia and low back pain, the present research was conducted in primary care^(16,17). This level of care may be the most appropriate for providing this type of intervention. It is important to note that group educational interventions are common in the primary care setting (e.g., for patients with diabetes, chronic obstructive pulmonary disease, smokers, etc.), and, in general, primary care professionals are experienced in this type of intervention.

For studies in which investigators cannot be blinded, Sutton et al.⁽¹⁸⁾ proposed that some follow-up visits should be recorded and subsequently compared.

In similar studies in which group educational or psychological interventions were evaluated, no



specific intervention was provided to control group participants other than usual medical care^(19,20). In addition, regardless of the effectiveness of the individual underlying components of the intervention, it was considered important to test the overall effectiveness of the group educational intervention compared to usual care^(21,22).

Conclusions

The study concludes that a group educational intervention could be an effective strategy for managing migraine, as it substantially reduces the number of days lost due to the condition, decreases pain intensity and reduces medication intake. In this way, primary care could be an appropriate setting for this group's educational intervention.

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