



Letter to editor

The importance of considering psychosocial aspects in migraine patients

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Recently we read the paper titled "The beneficial effect of positive treatment expectations on pharmacological migraine prophylaxis" by Katharina Schmidt and coworkers¹, published in the journal PAIN and available in 2021. We congratulate the authors for the interesting paper and contribution on the influence of patients' psychic conditions on migraine treatment.

In the article, patients were followed for 6 months, with surveys at study entry (T0, baseline), 1 week later after study entry (T1) by telephone, and online surveys at 1, 3, and 6 months after baseline. The primary outcomes were the number of headache days, migraine days, and adverse events by GASE score.¹ The secondary outcomes were pain intensity and duration, pain-related impairment depression, anxiety and stress, and quality of life. The study also considered migraine subtypes (chronic and episodic), patients' previous treatment experience, and genotype.¹

In general, participants showed improvement in headache and migraine symptoms during prophylactic treatment, and positive expectancy was associated with fewer headache and migraine days across all analysis time points. However, treatment efficacy was significantly increased by positive treatment expectancy only in chronic migraine, although expectancy was lower in this group compared with episodic migraine.

An important factor that must be considered in clinical trials for approaches to treat migraine is the placebo effect.^{2,3} Recently, a systematic review evaluated the association between the degree of response to placebo in migraine studies and the observed difference between drug and placebo across studies of preventive treatments for migraine.² In clinical trials of preventive treatments for migraine, higher placebo responses were associated with smaller placebo-subtracted response rates, and higher sample size requirements than trials with lower placebo responses.² According to the authors, in order to control the size of the placebo effect in clinical trials, the sample size must be increased.² Another aspect that can affect the results is the route of treatment administration.^{2,3} Studies with an oral treatment had slightly lower levels of placebo effect than studies with an injection treatment.² Clinical trials must distinguish an effective (or non-effective) treatment from a placebo.² Beside the placebo effect, the research team must consider the other factors that might favor the improvement of the painful.^{2,3} We can mention the Hawthorne effect (the tendency of people to change their behavior or condition simply as a consequence of being observed or studied), the regression to the mean, the natural course of the disease, and even a poor study design.^{2,3} Some theories about clinical trials suggest that expectation should increase the response in both treatment and placebo groups equally.² But, some studies indicate the opposite and the study groups might be affected unevenly.²

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From our point of view, the paper was particularly interesting because it considers treatment expectations and previous treatment experience. This is especially important considering that mental disorders such as anxiety and depression are particularly prevalent in this population.⁴ It is well known that psychiatric comorbidities are an important issue in the diagnosis and treatment of migraine and require different approaches.⁵ These conditions may also interfere with the prophylactic treatment of migraine in the belief that treatment is effective, even at the time of the medical appointment. Therefore, to consider appropriate treatment for a patient, the individual's mental health status and expectations must be examined.

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