

Commonly prescribed medicines no more effective than placebo for pediatric migraines

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Pills. Credit: Public Domain

Prescribed medications are no more effective than a sugar pill when used to prevent migraines in children and teens.

A study to be published Oct. 27 in *The New England Journal of Medicine* shows no significant differences among amitriptyline, topiramate and [placebo](#) in reducing headache days or related disability.

"The study was intended to demonstrate which of the commonly used preventive medications in migraine was the most effective. What we found is that we could prevent these headaches with either a medication or a placebo," says Andrew Hershey, MD, PhD, co-director of the Cincinnati Children's Headache Center and senior author of the study.

"This study suggests that a multi-disciplinary approach and the expectation of response is the most important, not necessarily the prescription provided."

Researchers conducted the Childhood and Adolescent Migraine Prevention (CHAMP) study at 31 sites in the United States.

Cincinnati Children's served as the Clinical Coordinating Center (CCC) for the study, and was responsible for all clinical oversight activities. The Clinical Trials Statistical and Data Management Center (CTSDMC) at the University of Iowa served as the Data Coordinating Center for the study. It had primary responsibility for data management, implementing the electronic data capture system, and all statistical aspects of the study.

The 24-week clinical trial included 328 eligible patients. The trial used a clinically meaningful endpoint of a 50 percent or greater reduction in

headache days from the 28 days prior to randomization to the final four weeks of the 24-week study. Sixty-one percent of those on a placebo saw the days they had a headache reduced by 50 percent or more.

For the two medication groups, 52 percent of those taking amitriptyline and 55 percent of those taking topiramate had this level of reduced headache days. The responder rates were not statistically different between the three groups.

Compared to placebo, those on the two active drugs had a significantly higher rate of side effects, including fatigue, dry mouth and, in three cases, mood alteration. Thirty-one percent of those on topiramate had paresthesia - a "pins and needles" tingling in the hands, arms, legs or feet.

The results raise questions about the best way to prevent migraines, particularly given that it's unethical to prescribe a placebo without the patient's knowledge, according to the authors. They add it's likely the expectation of responding to a medication may override the actual biochemical and pharmacological changes that are thought to occur with pharmacotherapy.

Major pediatric headache centers, such as Cincinnati Children's, incorporate a multi-disciplinary approach that includes acute therapy, preventive therapy and behavioral treatment in a systematic approach, says Hershey. The CHAMP study incorporated this approach across all 31 study sites to ensure uniformity.

The study authors stress that further studies need to be done to identify the optimal way to incorporate multi-disciplinary strategies. One of the preventive therapies often used is cognitive behavior therapy (CBT). CBT refers to a group of psychological treatments that are based on scientific evidence. While CBT has not been directly compared to a pill

placebo for pediatric migraines, neurologists and psychologists view it as a helpful and critical component in a treatment plan.

"Our national team was hoping to develop evidence to drive the choice by medical providers of the first line prevention medication for helping youth with [migraine](#), but the data showed otherwise, says Scott Powers, PhD, pediatric psychologist, co-director of the headache center at Cincinnati Children's, and first author of the paper. "We see this as an important opportunity for health care providers, scientists, children, and families because our findings suggest a paradigm shift. First line prevention treatment will involve a multidisciplinary team approach and focus on non-pharmacological aspects of care. The good news is we can help children with migraines get better."

Powers says the study also underscores the importance of conducting more research with a developmental focus on children and young adults. This will allow innovations that can be applied directly to a chronic illness of childhood.

"The interpretation of these results is very challenging. In most situations, trials that fail to show benefit of an intervention do so because study participants do not improve. That was not the situation here. A majority of all study participants improved, regardless of their assigned treatment group," says Chris Coffey, PhD, director of the CTSDMC and professor of biostatistics in the University of Iowa's College of Public Health, and lead statistician for the study. "Further research is needed to better understand the results and to determine what future strategies might optimize the treatment of headaches in these childhood and adolescent populations."

Provided by Cincinnati Children's Hospital Medical Center

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