

YES, THE PLACEBO IS USEFUL AND IMPORTANT IN HEADACHE TREATMENT AND RESEARCH

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The factors that affect the placebo response have not been systematically studied yet appear to be many and varied. In addition, recent findings regarding neurochemical and functional changes in the brain secondary to placebo make this an important area of study. Such results highlight the validity of the placebo response and underscore the need to better understand this variable in both research and clinical settings. This is important in Headache Medicine as well as in the study of other disorders.

Given its presence in almost every clinical trial, the placebo is the most frequently studied substance in clinical research. Demonstration of treatment efficacy demands that the target (active) agent must be shown to be statistically significantly superior to an inert substance (placebo) not believed to be a specific therapy for the target condition. This is the “gold standard” in clinical research. Placebo rates (and factors that influence them) become increasingly important as potential methodological manipulations (e.g., “over-powering” clinical studies) may allow small differences between groups to reach statistical significance when, in fact, such differences may be clinically meaningless. Similarly, placebo rates have been shown to vary dramatically depending upon the type of treatment (e.g., degree of invasiveness).

Placebo-related variables help to create “non-specific” treatment factors that contribute to treatment efficacy in clinical settings. Enhancing these variables is desirable to maximize the likelihood of therapeutic benefit. Variables that contribute to “positive expectations” have been proposed as desirable but have not been systematically studied. Clinicians should make every effort to maximize placebo effects of whatever treatment is utilized.

Finally, there is an emerging literature regarding the prevalence and importance of clinicians across diverse areas of medicine who practice what is called “Placebo Medicine”. Such practices employ and support the use of “placebo’s” (defined as agents that have no evidence-base for improvement in a patient’s condition) as useful tools when there are no other treatments are available. The notion that such treatments “won’t hurt and are worth a try” has been shown to be embraced by clinicians who treat a variety of disorders. In Headache Medicine, the use of “off-label” medications is commonplace and part of mainstream headache treatment protocols.

In sum, issues related to placebo are extremely important variables in both clinical and research settings. Treatment with placebo is frequently effective and cannot be considered “no treatment”. Systematic study of issues that impact the positive (and negative) effects is relevant to enhance and improve patient care and to provide greater validity and generalization of research results.