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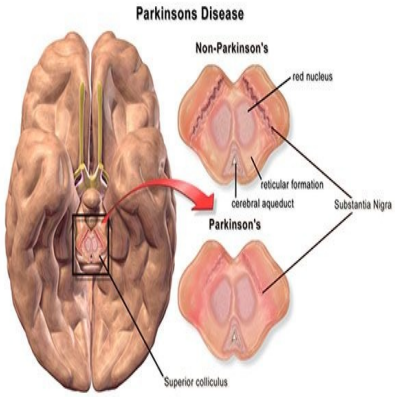
Mapping Technique for Modulation Following Sham Surgery



Researchers at the Feinstein Institute for Medical Research have identified a new image-based strategy that can be used to identify and measure placebo effects in randomised clinical trials for brain disorders. These findings have been published in the August issue of The Journal of Clinical Investigation. The research team, led by David Eidelbery, MD, successfully developed a method that identifies brain patterns that are abnormal or indicate disease using imaging techniques. This method has been used in patients with Parkinson's disease and other neurodegenerative disorders.

To date, the diagnosis of Parkinson's disease is based on the clinical examination of the patient by a skilled and experienced neurologist. The fact that Parkinson's disease is the second most common neurodegenerative disease in the US highlights the need for more effective diagnostic tools and treatment options for the disease.

A major obstacle to the development of effective therapies for brain disorders such as Parkinson's Disease has been patient responses to placebo and sham effects. Placebo or sham surgical responses are quite frequently encountered in trials of new treatments for disorders such as Parkinson's. These effects have played a role in the failure of several blinded, early phase clinical trials of novel interventions.

In this study, functional brain imaging and network analysis was used to study the circuitry underlying placebo effects in patients with Parkinson's Disease. This metabolic imaging was performed prior to randomisation followed by another one at six months and 12 months after sham surgery. The sham response was associated with the expression of a cerebello-limbic circuit. All patients participating in the study were scanned for 10 minutes, beginning 30 minutes after radiotracer injection. The patients were in an awake-resting state with their eyes open at the time of the scanning. The scanning was conducted in a dimly lit room with minimal auditory stimulation.

Dr. Eideberg talks about this new strategy, "One of the major challenges in developing new treatments for neurodegenerative disorders such as Parkinson's disease is that it is common for patients participating in clinical trials to experience a placebo or sham effect. When patients involved in a clinical trial commonly experience benefits from placebo, it's difficult for researchers to identify if the treatment being studied is effective. In a new study conducted by my colleagues and myself, we have used a new image-based strategy to identify and measure placebo effects in brain disorder clinical trials."

The study was conducted under blinded conditions and correlated with the sham subjects' outcome. The network changes were reversed when the subjects learned of their sham treatment status. Each patient's network expression value measured before the treatment was used to predict his subjective blinded response to the sham treatment. It was thus concluded that this new and unique image-based measure of the sham-related

network could potentially reduce the number of patients that are assigned to sham treatment in randomised clinical trials, and can help exclude patients who are more likely to display placebo effects under blinded conditions.

Source: ScienceDaily
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