Clinical Trial Tests Possible Benefits of Brain Stimulation on Hand and Arm Movement Following Stroke

Shepherd Center

New Approach Could Change Common Practices of Care for Certain Stroke Patients

 Researchers at Shepherd Center are studying whether stimulating the brain before rehabilitation could yield greater gains in motor function for people recovering from stroke.

Shepherd Center is one of 12 U.S. centers participating in a clinical trial that is evaluating whether coupling navigated transcranial magnetic stimulation (TMS) of the brain with standard occupational therapy can measurably improve hand and arm function following a stroke. Experts say this approach could unlock a totally new, non-invasive treatment to promote recovery and function.

“It’s really a seminal study in neurorehabilitation that, if successful, will change common practices for how we take care of certain stroke patients,” said Ford Vox, M.D., a physical medicine and rehabilitation physician at Shepherd Center and primary investigator for this study. “We have this golden opportunity right after someone has a stroke when we know people are most likely to improve or recover function, and this therapy may offer patients the best potential.”

Shepherd Center is testing a navigated brain stimulation system developed by a Finnish medical technology company called Nexstim. It uses TMS therapy to apply a mild electromagnetic current to excite the brain, a technique that can be used to both investigate the brain’s functions and change them. The technique is growing in

popularity as a way to map the brain before surgery and as a treatment for depression. Nexstim's device provides visual guidance to the operator, who uploads and correlates MRI pictures of the patient's brain with the device's infrared guidance system. Then, the device creates a 3-D model of the patient's brain, pinpointing the target site for stimulation in real time (called stereotactic guidance).

In this new trial, clinicians believe TMS works by slowing activity in the healthy area of the brain, which can become overly active following a stroke, causing detriment to the injured side.

"By reducing brain activity on the side of the brain that was not injured, the injured side may actually have a better chance of recovery," Dr. Vox explained.

The technology is akin to a more advanced version of constraint-induced therapy in which clinicians physically tie down a patient's good arm, which forces the patient to use the injured side. With Nexstim's non-invasive device, researchers are using electromagnetism to slow activity in portions of the healthy brain hemisphere that control the uninjured arm, similarly forcing the brain to use its injured half.

"People who have experienced a stroke often have limited resources and rehabilitation benefits," Dr. Vox noted. "If initial results are confirmed, patients might be able to get that much more out of the limited time they have with therapists by using this technology."

Eligible clinical trial participants receive either the navigated brain stimulation or a sham (simulated) treatment in conjunction with six weeks of hand and arm therapy provided by an occupational therapist. Researchers and study participants do not know whether they are in the treatment or simulation group. Visits start with 20 minutes of standardized, task-oriented activity followed by the treatment or simulated therapy and then an hour of upper-limb rehabilitation therapy.

The goal is to improve a patient's range of motion, coordination, flexibility, strength, and use of the weak arm and hand. Specifically, researchers are interested to see whether – at the end of the study – patients are better able to perform daily activities, such as dressing, grooming, cooking, doing laundry, writing, typing and leisure activities. For example, is a patient now able to button a shirt that he couldn't before, open a jar or screw-top bottle, pour beverages, manipulate keys to lock and unlock doors, use a phone or fold laundry?

In a similarly designed pilot study of the device conducted at the Rehabilitation Institute of Chicago, researchers found striking improvements in motor function among people receiving the targeted stimulation compared with those in the simulation group. At six months post-stroke, these patients were 30 percent more likely to have meaningful arm recovery (80 percent compared with just 50 percent). Researchers presented their findings in February 2014 at the American Heart Association and the American Stroke Association's International Stroke Conference. (Read the abstract. [1])

"It was eye-opening to see patients reach their rehabilitation goals like being able to

pick up coins from a table," said Janne Huhtala, CEO of Nexstim, which is funding the study. "It sounds simple for a healthy person, but can make a real difference if you are suffering from the deficits caused by a stroke."

Researchers hope the current clinical trial, which will enroll up to 200 patients, will replicate the initial findings. Dwayne Nelson, one of the participants in the first study, said: "It's just immeasurable the progress that I have made. I can reach, and when I grasp, I have more control."

To date, therapeutic TMS has been primarily used in patients with major depression who are resistant to medications. But there has been increasing interest in its use with other types of neurological disorders.

"We are excited to be involved in this trial," Dr. Vox said. "If the trial proves successful, it represents a big moment in this field of medicine: For the first time we could have an FDA-approved form of noninvasive brain stimulation to help people with stroke by promoting concrete motor improvements."

Strokes happen when the blood supply to the brain is blocked or when a blood vessel in the brain ruptures, causing brain tissue to die. Stroke is a major cause of disability in adults, according to the American Heart Association. Nearly 800,000 Americans experience a stroke each year; only about 50 percent of stroke survivors recover full use of their affected arm.

Dr. Vox suspects that if the Nexstim device proves effective, there will be other clinical uses down the line. Future research may also investigate its role in patients with no movement.

Links:
[1] http://stroke.ahajournals.org/content/45/Suppl_1/A152?related-urls=yes&legid=strokeaha;45/Suppl_1/A152