Parkinson treatment shows positive results in clinical testing

GAINESVILLE, Fla. - Researchers from the University of Florida and 14 additional medical centers reported results today in the online version of The Lancet Neurology journal indicating that deep brain stimulation - also known as DBS - is effective at improving motor symptoms and quality of life in patients with advanced Parkinsons disease.
The study, sponsored by St. Jude Medical Inc., tested the safety and effectiveness of a constant current DBS device developed by St. Jude Medical to manage the symptoms of Parkinsons disease. The device aimed to reduce tremors, improve the slowness of movement, decrease the motor disability of the disease and reduce involuntary movements called dyskinesia, which are a common side effect of Parkinsons drugs.

After treatment, analysis of 136 patient diaries revealed longer periods of effective symptom control - known as "on time" - without involuntary movements. "On time" for patients who received stimulation increased by an average of 4.27 hours compared with an increase of 1.77 hours in the group without stimulation. Patients also noted overall improvements in the quality of their daily activities, mobility, emotional state, social support and physical comfort.

"I think it is safe to say since dopamine treatment emerged in the 1960s, DBS has been the single biggest symptomatic breakthrough for Parkinson patients who have experienced the fluctuations associated with levodopa therapy," said Michael S. Okun, M.D., first author of the study, administrative director of the UF College of Medicines Center for Movement Disorders and Neurorestoration, and the National Medical Director for the National Parkinson Foundation. "This study validates the use of mild electrical currents delivered to specific brain structures in order to improve Parkinsons disease in select patients with advanced symptoms, and additionally, it explored a new stimulation paradigm. Future improvements in devices and the delivery systems for DBS will hopefully provide exciting new opportunities for Parkinsons sufferers."

Only patients who have had Parkinsons disease for five years or more were included in the study. They were randomly assigned to a control group that delayed the onset of stimulation for three months, or a group whose stimulation began shortly after surgery. All patients were followed for 12 months.

The deep brain stimulation procedure involves surgeons implanting small electrodes into an area of the patients brain that controls movement. The electrodes are connected to a device precisely programmed to use mild electrical current to modulate problematic brain signals that result in movement problems.

Todays voltage-controlled DBS devices deliver pulses of current that vary slightly

with surrounding tissue changes. The DBS devices tested in this study are intended to provide more accurate delivery and control of the electrical pulses.

"We are committed to driving research that will provide solutions for physicians and their patients whose needs are currently unmet," said Rohan Hoare, president of St. Jude Medical Neuromodulation Division. "These results are significant as they offer evidence that stimulation with the Libra constant current system enabled patients to have better motor control and an improvement in their quality of life when compared to the control group."

The U.S. Food and Drug Administration approved the use of DBS for Parkinsons disease in 2002. At least 500,000 people in the United States suffer from Parkinsons with about 50,000 new cases reported annually, according to the National Institute of Neurological Disorders and Stroke. These numbers are expected to increase as the average age of the population rises.

"The study answered some very important questions concerning cognition and mood with lead implantation (alone) versus implantation with stimulation. It also refutes the hypothesis that DBS increases depressive symptoms," said Gordon H. Baltuch, M.D., Ph.D., a professor of neurosurgery in the Perelman School of Medicine at the University of Pennsylvania and a study author. "The groups results also showed a decrease in the infection rate to 4 percent from previously published 10 percent. It shows that American neurosurgeons and neurologists with their industry partners are improving the safety of this procedure and working in a collaborative fashion."

Comparable with other large DBS studies, the most common serious adverse event revealed was infection, which occurred in five patients. Likewise, some participants also reported an increase in the occurrence of slurred speech, known as dysarthria.

"Technology is on the move, and we expect to see continued improvements to DBS approaches, equipment and materials," said Okun, who is also affiliated with UFs McKnight Brain Institute. "DBS has set the bar high for the development of new therapies for advanced Parkinsons disease patients. DBS will be the standard of care gene therapy and other cell-based therapies that are now being conceived will be measured against, and this will hopefully translate into significant improvements in what we can offer our patients."

In addition to UF and Penn, research was conducted at centers affiliated with Baylor College of Medicine, Columbia University Medical Center, Lahey Clinic, Loma Linda University Medical Center, the Medical College of Wisconsin, Mount Sinai Medical Center, Oakwood Hospital and Health Systems, Texas Health Presbyterian, Rush University Medical Center, the University of Miami, the University of Rochester and the University of Virginia Health Systems.

Posted by Sean Fenske, Editor-in-Chief, MDT