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News Release

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VA-NIH Study Offers Hope for Parkinson's Patients *Study Says Deep-Brain Stimulation Has Benefits*

WASHINGTON -- Electrical stimulation of the brain -- a treatment in which a pacemaker-like device sends pulses to electrodes implanted in the brain -- is riskier than drug therapy but may hold significant benefits for those with Parkinson's disease who no longer respond well to medication alone.

That is the conclusion of researchers from the Department of Veterans Affairs (VA) and National Institutes of Health (NIH) who conducted a six-year study comparing deep-brain stimulation (DBS) to medication, along with speech, physical or occupational therapy, given as needed. The results of the trial, the largest of its kind to date, appear in the January 7 *Journal of the American Medical Association (JAMA)*.

"Deep-brain stimulation offers hope for a large number of patients with advanced Parkinson's disease who suffer from complications of long-standing medication therapy," said Secretary of Veterans Affairs Dr. James B. Peake. "This finding could mean improved quality of life for some of our patients."

The study included 255 Parkinson's patients at seven VA medical centers and six university hospitals. The VA sites were Portland, Ore., Seattle, San Francisco, Los Angeles, Houston, Richmond, Va., and Philadelphia, all members of VA's network of Parkinson's Disease Research, Education and Clinical Centers.

The *JAMA* article also noted VA's nationwide system of hospitals and specialized centers of excellence make the Department uniquely capable of conducting such large, multi-site trials of new therapies and medical devices. VA's patient population is especially suited for trials of treatments for chronic disease in the elderly.

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Deep Brain Stimulation 2/2/2/2

Patients who took part in the study were on medication but are no longer seeing improvements in symptoms such as tremors or stiffness. Many were also developing side effects from the drugs, such as involuntary face, arm or leg movements.

Researchers followed the patients for six months, finding:

- Patients who received DBS gained an average of 4.6 hours per day of good motor control and few or no involuntary movements, compared with no gain for those on medical therapy alone;
- 71 percent of DBS patients showed significant gains in motor function, compared with only 32 percent of drug therapy patients; and
- Serious adverse side effects were nearly four times more common in the DBS group, but almost all of these effects in both groups were resolved during the six-month study. The most common side effects from DBS were infections, falls, depression, gait and balance problems, and pain.

Lead authors and study co-chairs were Frances Weaver, PhD, a researcher with the Center for Management of Complex Chronic Care at the Hines VA Hospital near Chicago, and Dr. Kenneth Follett, a neurosurgeon at the Omaha VA Medical Center and University of Nebraska. They emphasize that besides the higher likelihood of serious side effects with DBS compared with drug therapy, another drawback of the procedure is that, although it generally improves movement, it does little to help other Parkinson's symptoms such as depression, decline in mental ability, gait and balance problems, and trouble with gastrointestinal, urinary or sexual function.

“The results of the study should not be over- or under-stated,” said Dr. Michael Kussman, VA's Under Secretary for Health. “Still, there are many good candidates for DBS among patients with Parkinson's disease whom we treat in VA.”

The trial was sponsored by VA's Cooperative Studies Program and the National Institute of Neurological Disorders and Stroke, part of the National Institutes of Health. Additional support came from Medtronic, which makes the DBS system used in the study.

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Deep Brain Stimulation 3/3/3/3

Parkinson's disease, a progressive neurological disorder, affects some 1.5 million Americans, with 50,000 new cases diagnosed annually. VA treats at least 40,000 veterans with the disorder each year. Most patients are over age 50, but some forms of the disease can strike younger adults.

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