SOUTHWESTERN NEWS

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VAGUS NERVE STIMULATOR SUCCESSFUL FOR DEPRESSION

DALLAS – December 15, 1999 – A nationwide clinical trial has shown Vagus Nerve Stimulation (VNS), an electrical stimulation therapy currently used to combat epilepsy, to be a promising new method for treating patients with severe treatment-resistant depression.

Results of the VNS pilot study showed that 40 percent of the treated patients displayed at least a 50 percent or greater improvement in their condition, according to the Hamilton Rating Scale for Depression, said Dr. A. John Rush, vice chairman for research in the Department of Psychiatry at UT Southwestern Medical Center at Dallas and the study's lead investigator. Half the patients also had at least a 50-percent improvement on the Montgomery Asberg Depression Rating Scale. The condition of several patients improved so substantially that they were able to return to work or other normal activities. All the patients who responded to the treatment have continued to do well.

Results of the 30-patient study were published online today in *Biological Psychiatry* in abstract form. Besides UT Southwestern, the clinical study was conducted at Medical University of South Carolina College of Medicine, Charleston; Columbia University College of Physicians and Surgeons and the New York State Psychiatric Institute, New York; and Baylor College of Medicine, Houston.

Approximately 18 million Americans suffer from depression, about 1 million of whom have severe treatment-resistant depression.

"While the results are preliminary, since the study included only 30 participants, they are extremely encouraging and point toward the importance of conducting further research in this treatment area," said Rush.

He also said that test results indicate that the treatment may have the potential to be used as an alternative to electroconvulsive therapy for some patients.

"For the first time in years, I can feel joy, real joy," said Joanne Tesoriero, a Texas grandmother treated during the pilot study and a lifelong sufferer of chronic depression. "VNS has enabled me to do what years of drugs and even ECT has not. I can fully appreciate my

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family, my children and my grandchildren. It is the best thing I have ever done."

The Food and Drug Administration has approved an expanded, 94-patient trial of VNS at up to 15 medical centers to begin next year. Houston-based Cyberonics, which helped fund the research, developed the treatment and devices. The firm has said that the study may ultimately involve 200 patients at up to 20 medical centers. The NCP System used to deliver VNS is not currently approved for the treatment of depression.

"The vagus nerve carries information to many areas of the brain that control mood, sleep and other functions," Rush said. VNS treatment involves stimulating the left vagus nerve in the neck with a series of miniscule electrical pulses traveling through a small surgically implanted wire attached to a pulse generator in the chest. The pulse generator delivers stimulation to the vagus nerve in individualized therapeutic "doses."

Study patients were required to be from 18-70 years of age and to be suffering from non-psychotic major depression or be in the depressed phase of bipolar, or manic-depressive, illness. Participants' current episodes had to have been more than two years in duration, or they had to have suffered at least four different episodes. They also had to have failed to respond to at least two medication trials in the current episode. Patients who were currently taking psychotropic medications were allowed to continue on their prescriptions.

Following surgery to implant the pulse generator in the upper chest and tunnel the wires into the neck, where they were wrapped around the left vagus nerve, patients received no electrical stimulation while they healed, a two-week period for most.

"At the end of that time, the levels of electrical impulses were adjusted for individual patient tolerance, this process also taking two weeks," Rush said. Then the patients received VNS for an eight-week period, each receiving his or her individually tolerated dose.

Besides Rush, UT Southwestern researchers included Dr. Mustafa Husain, associate professor of psychiatry; nurse Diane Stegman in psychiatry; and Dr. Cole Giller, associate professor of neurological surgery. Other authors included Dr. Harold Sackeim at Columbia; Dr. Mark George at the Medical University of South Carolina; and Dr. Lauren Marangell at Baylor.

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