

SOUTHWESTERN NEWS

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EMBARGOED UNTIL 12:01 A.M., CDT, WEDNESDAY, AUG. 31, 2005

VNS therapy for treatment-resistant depression proves effective for some patients

DALLAS – Aug. 31, 2005 – Vagus nerve stimulation (VNS) therapy, a treatment recently approved by the Food and Drug Administration for treatment-resistant depression, produced a positive response in more than 25 percent of patients in a national, yearlong study led by UT Southwestern Medical Center psychiatrists.

Sixteen percent to 20 percent of the study group experienced total remission.

Results of the study, led by Dr. A. John Rush, vice chairman for research in psychiatry at UT Southwestern, appear in the September issue of *Biological Psychiatry*. Findings from two additional related studies also are included in the issue.

VNS therapy, which the FDA approved for treatment of epileptic seizures in 1997 and for depression in July, has been studied in clinical trials for treatment-resistant depression since 1998. VNS therapy includes surgical implantation of a small battery-operated pulse generator – similar to a pacemaker – in a patient's left upper chest. Thin, flexible wires from the device are tunneled into the neck and send mild, intermittent pulses to the neck's left vagus nerve. The vagus nerve in turn delivers these pulses about every five minutes to the areas of the brain involved in the regulation of mood, motivation, sleep, appetite and other symptoms relevant to depression.

Karmen McGuffee, who had the vagus nerve stimulator implanted in 1999 after suffering from severe depression for more than 15 years, said the device has restored her life. A participant in one of the first clinical trials at UT Southwestern, she had taken more than 10 types of antidepressant drugs before the surgery, with little success.

"It was like having the color come back into my world," said Mrs. McGuffee, 35. "Before VNS therapy, I could barely function and only then with a lot of help. At the time, I had nothing to lose.

"Now I feel brighter and lighter. I'm not constantly worried, and I look forward to everyday activities. Things that other people take for granted, such as managing a house, a family and a job all are now possible."

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VNS therapy is only indicated for people who have not been helped by other depression treatments, said Dr. Rush. “If you have treatment-resistant depression and need long-term treatment, VNS is an option that should be considered. While it’s not going to get everybody into remission, it’s doing pretty well in very difficult-to-treat patients,” he said.

Two of the three studies in the current journal compared patients with major depressive disorder or bipolar disorder, all of whom were implanted with the vagus nerve stimulator. In the first trial, which included 235 people and only lasted for 10 weeks, patients implanted with the stimulator received either active VNS therapy or no therapy, meaning the device was not activated. There was little change in either group.

Dr. Rush’s second multicenter trial, which included 205 of the same patients, provided active VNS therapy for a full year to all participants, measuring their symptoms of depression at regular intervals using several standard rating scales. One rating scale showed a 27.2 percent reduction in symptoms among participants and a 15.8 percent remission rate at year’s end – suggesting that long-term treatment with VNS offers a greater benefit than its short-term application. A second rating scale showed reduction in symptoms by 28.2 percent and a 20.3 percent remission rate.

“This is a very good response, given the type of highly resistant depression involved,” Dr. Rush said. “Participants in the trials were some of the most treatment-resistant depressed patients ever studied, with at least half having been hospitalized for the disease at least once.”

The studies also showed VNS to be well-tolerated, with few serious adverse reactions, he said. Possible side effects, however, can include a slight voice alteration or temporary hoarseness, cough, tickling in the throat or shortness of breath during exertion – symptoms which may occur intermittently when the stimulation is on.

The third study, of which Dr. Rush was a co-author, compared two groups of people with similar degrees of severe depression. One group was implanted with the vagus nerve stimulator as well as given other types of treatments for depression, including medication and cognitive therapy. The second group did not receive the device, but was treated for depression. Results showed a 27 percent reduction in depressive symptoms in the VNS group, compared to a 13 percent reduction in the second group.

Dr. Mustafa Husain, professor of psychiatry and internal medicine at UT Southwestern, said VNS offers “new hope” for severely depressed individuals.

“VNS treatment can be very useful in combination with antidepressants for a particular group of patients who are chronically depressed,” he said. “It can provide new hope for a better life to those who are not responding to antidepressant medications.”

Dr. Husain and Dr. Rush were involved in all three studies, which included researchers from more than 20 sites around the country. The studies were supported in part by Cyberonics Inc., manufacturer of VNS Therapy.

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