



Media Contact: Sandra Van
Telephone: 1-800-880-2397
E-mail: sandy@prpacific.com

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HIGHLIGHTS:

Vagus nerve stimulator (VNS) implantation, used in the treatment of epilepsy for nine years, was recently approved by the Food and Drug Administration as an option for patients suffering from treatment-resistant depression. Cedars-Sinai Medical Center's departments of Psychiatry and Neurosurgery are collaborating to provide this therapy as an "alternative for some people who don't have many choices."

SURGICAL PROCEDURE IS AN ADDITIONAL TOOL FOR SOME CASES OF TREATMENT-RESISTANT DEPRESSION

LOS ANGELES (Feb. 3, 2006) – Cedars-Sinai Medical Center is among the first centers in Southern California to begin offering vagus nerve stimulator (VNS) implantation as a potential supplement to traditional therapies for treatment-resistant depression. The device, used in epilepsy treatment for nine years, was approved by the Food and Drug Administration (FDA) last year for treating depression.

"Cedars-Sinai psychologists and psychiatrists are available to consult with patients and treatment professionals in the community, provide evaluations and screenings, and refer appropriate candidates to the neurosurgeons for surgical intervention," said Keith L. Black, M.D., director of the Division of Neurosurgery. "Psychiatrists will program and monitor the stimulators to provide ongoing management of VNS as one element of the treatment plan."

Implantation of the stimulator is an outpatient operation that takes only about 45 minutes. Two incisions are made – one in the neck, beside the Adam's apple, and the other in the chest. An electrode is wrapped around the vagus nerve in the neck, and a pulse generator, which is similar to a heart pacemaker, is implanted in the chest. With the wires connecting the two components tunneled under the skin, there are no external, visible parts.

Once the patient's incisions have healed, the device is turned on, sending intermittent, preprogrammed, mild electrical pulses through the vagus nerve into the brain. Although results are not immediate and many patients do not respond at all, a significant number eventually feel relief.

"This is a new treatment modality that may help about one in three people with very severe depression," said Mark H. Rapaport, M.D., chairman of Cedars-Sinai's Department of Psychiatry, noting that studies are underway to determine if there are predictors that will help psychiatrists identify which patients are most likely to have a good response. "When you consider that chronic, severe depression is associated with both increased morbidity and increased mortality, giving somebody a one in three chance of feeling a lot better is a considerable improvement, and it is a hope we can offer."

Rapaport participated in a major clinical trial that led to the FDA's decision to approve VNS for depression. In that study, half of the patients undergoing VNS implantation had the device turned on two weeks after

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surgery. The other half had the device implanted but not turned on immediately. Patients were not informed which group they were in, and at three months, there was little discernable difference between the two groups. In fact, a difference was evident only on the more sensitive of two inventories used to evaluate depression.

But at the three-month point, the second group's devices were turned on, with other appropriate medications and therapies continuing as usual. And at one year post-surgery, members of both groups were compared to patients who had qualified to participate in the study but did not undergo the operation.

"We found that of the group that had VNS plus appropriate care, about a third had significant, sustained improvement. In contrast, the group of people with sustained improvement in the medication-alone group was about 10 percent," said Rapaport. "If you look at the progression of change in the VNS data, you see that individuals who are going to respond typically begin to show a response somewhere between months three and six. Some people respond early, but the vast majority of people respond between months three and six, with a few more responding at month nine. So it takes time for VNS to work, and that makes sense because it takes time for people to heal."

Psychiatrist Robert M. Cohen, M.D., Ph.D., director of Clinical Research and associate director for Research in the Department of Psychiatry, emphasizes that VNS is one option among many to be considered. "The benefit of VNS is that you don't have to withdraw patients from any of their current medications, and you can still work toward increasing the effectiveness of their drug treatment. It's like having an additional weapon, but you're not taking away any of the other weapons. That's what I try to emphasize about this procedure. It's something to be added, but that doesn't mean we stop trying in the other dimensions such as psychotherapy, changes in medication management or ECT (electroconvulsive therapy)."

"We're careful not to oversell the procedure. Based on studies, 10 percent of people with treatment-resistant depression might over two years have a marked clinical improvement without VNS. With VNS, 33 percent will have marked clinical improvement, meaning that perhaps only 23 percent more individuals are improving than would have improved anyway. VNS does not prevent anyone from having a spontaneous or psychotherapy induced change. It just adds something to help them, and hope is very important. You never want to take away hope from any patient or family in terms of an illness, and certainly in terms of depression. For many individuals, this treatment provides some hope," said Cohen, who also serves as chief of Research for Dementia and Neurodegenerative Diseases in the Department of Imaging.

"We conduct a very, very careful review of medical records, plus a very thorough evaluation, usually by two psychiatrists, prior to recommending this procedure for a patient," said Rapaport. "I think VNS probably has the potential to help a lot of people but one has to be careful about who one offers it to and also be sure that people are truly informed about the benefits and the potential – that only about one in three will truly benefit at this time."

VNS was approved by the FDA for treatment of refractory epilepsy in 1997. Physicians noted that patients' moods also appeared to improve, which led to clinical trials and last year's approval for use of VNS in treatment-resistant depression.

"This is a simple device to put in, is very safe, and may be an alternative for some people who don't have many choices," said Adam N. Mamelak, neurosurgeon, who has performed the same operation many times as a treatment for epilepsy. He and neurosurgeon Ajay K. Ananda, M.D., specialize in the procedure.

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Western United States. For 18 consecutive years, it has been named Los Angeles' most preferred hospital for all health needs in an independent survey of area residents. Cedars-Sinai is internationally renowned for its diagnostic and treatment capabilities and its broad spectrum of programs and services, as well as breakthroughs in biomedical research and superlative medical education. It ranks among the top 10 non-university hospitals in the nation for its research activities and was recently fully accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). Additional information is available at www.cedars-sinai.edu.

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