

## From the annual meeting of the American Psychiatric Association (APA)

### Presentations featured VNS Therapy and treatment-resistant depression (TRD)

From May 19 to 24, 2007, thousands of psychiatrists attended the annual meeting of the American Psychiatric Association (APA) in San Diego, California. Several presentations at this major gathering of mental health specialists discussed TRD and the role of VNS Therapy.

#### Vagus nerve stimulation

A medical education course on May 20 addressed the growing interest in the use of VNS Therapy for mood disorders and other conditions. A team of 5 psychiatrists, led by Ziad H. Nahas, MD, of the Medical University of South Carolina, Charleston, began by describing the anatomy of the vagus nerve and associated brain regions. Presentations covered the clinical data for VNS Therapy in TRD. In a hands-on workshop, the psychiatrists attending the course learned dosing strategies for VNS Therapy.

#### National Advocacy Group Meetings

Associations for patients and their friends and families have meetings too. Mark your calendar with these events.

##### Mental Health America (formerly the National Mental Health Association)

- "Bringing Wellness Home"
- June 6–9, Washington, DC
- More information at [www.nmha.org](http://www.nmha.org)

##### National Alliance on Mental Illness (NAMI)

- "Building our Movement, Building our Future"
- June 20–24, San Diego, California
- More information at [www.nami.org/template.cfm?section=convention](http://www.nami.org/template.cfm?section=convention)

##### Depression and Bipolar Support Alliance (DBSA)

- "Making the Recovery Connection"
- August 10–12, Orlando, Florida
- More information at [www.dbsalliance.org/site/PageServer?pagename=home](http://www.dbsalliance.org/site/PageServer?pagename=home)

Another symposium the same day discussed treatments using brain stimulation; some treatments already approved for use in TRD (like VNS Therapy) and others still under investigation. Chaired by Charles B. Nemeroff, MD, PhD, of the Emory University School of Medicine, Atlanta, Georgia, "Caring for our Most Challenging Patients with Depression" discussed how to diagnose TRD, compared and contrasted treatments for it, and provided insight into how these treatments work.

#### TRD and STAR\*D

The APA meeting also featured reports from the landmark Sequenced Treatment Alternatives to Relieve Depression (STAR\*D) trial. Sponsored by the National Institute of Mental Health, STAR\*D is the largest and longest study ever to evaluate depression treatments.

Several meetings presented recent information from STAR\*D. They focused on key findings from the 4 levels of treatment in STAR\*D, the unmet needs of people with TRD, and the use of both drug and non-drug treatments (including VNS Therapy) to help people with depression achieve remission.

#### INSIDE

- Meet the patient
- Ask the doctor
- **NEW FEATURE!**  
Access Tips
- Tips for those who toss and turn



### Meet Lisa, a VNS Therapy patient

Now 38, Lisa first experienced symptoms of depression during puberty. The West Virginia native felt emotionally detached, lonely, and sad—even suicidal. Despite these feelings, Lisa did not seek or receive treatment until 1999.



In 2002, Lisa was hospitalized with depression for 4 days. Despite multiple medications, her condition failed to improve. She often stayed home, sleeping all day and awake all night, unable to control her thoughts. In March 2002, she left her job and went on short-term disability.

Even electroconvulsive therapy (ECT) proved ineffective against her depression and it caused memory loss.

In 2003, for the first time, her condition improved. A new combination of medications at a new clinic enabled her to function well enough to return to work. For the next 2 years, Lisa's depression was manageable and she held down a steady job.

But in July 2005, the cloud of misery and depression found Lisa again. The worst symptoms she had ever experienced put her back on disability.

Lisa's psychiatrist recommended VNS Therapy. After learning more about this treatment, Lisa agreed to try it. With a nurse case manager from Cyberonics, Lisa began trying to secure reimbursement coverage for the procedure. For 4 months, Lisa and her case manager battled initial denials for coverage while Lisa continued to struggle through each day.

Because Lisa's employer is a self-funded organization, she discussed her situation with a representative from her company's Employee Assistance Program (see more about this under Access Tips on this page). Lisa explained TRD and its impact on her. On December 19, 2005, Lisa's employer decided to overturn the denials from the healthcare plan—and pay for the treatment. She had the procedure 10 days later.

Within a few weeks of the procedure, Lisa's outlook on life improved. Soon, she could even return to work. By the end of June 2006, the black cloud of depression that had followed her since her teenage years had lifted.

She now describes herself as depression-free. "I feel like a kid again," she said.

Lisa puts in a full 40-hour workweek and has even returned to college after 19 years. Pursuing a major in business administration, she can read, understand, and analyze her textbooks, something she never dreamed of doing before receiving VNS Therapy. "I'm grateful that my employer paid for the treatment that gave me my life back," she said.

### Access tips

#### Can my employer help me gain insurance coverage?

Some employers have provided individual coverage for VNS Therapy after their health plans have denied coverage. These cases involved self-funded plans, where an employer or union pays a substantial portion of the cost of medical expenses. Not all employers are self-funded. To find out whether your employer is, contact your human resources department.

Before your employer's benefits manager decides to recommend coverage for VNS Therapy, you may have to explain TRD and VNS Therapy. You may also need to compile the following information for your employer:

- A letter of medical necessity from your psychiatrist and any appeal letters
- Copies of denial letters and any other correspondence from your health plan
- Pharmacy records and explanations of benefits for antidepressant treatments
- Appeal letters from you and/or your family members (if possible)
- Letter from your therapist, if you have one
- Your approval for your psychiatrist and your Cyberonics nurse case manager to speak with your human resources department

Cyberonics nurse case managers are available to assist you. Call **877-NOW-4VNS** (1-877-669-4867) for more information.

**Ask the doctor**

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**I've been depressed for so long—will VNS Therapy work for me?**

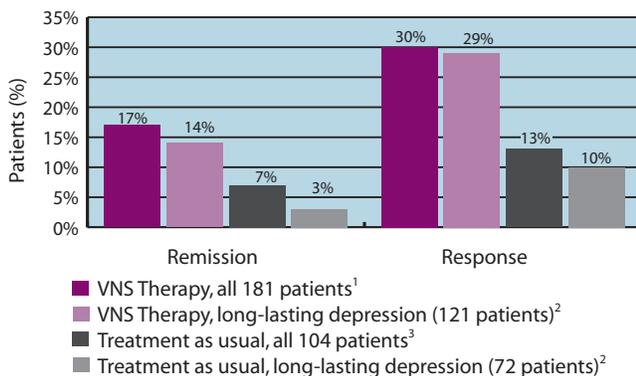
People who've been depressed for a long time can find it hard to believe that anything will ever work. But VNS Therapy is one treatment option shown to succeed where other treatments have failed, even after many years of depression.

The 205 people evaluated in the major clinical study of VNS Therapy had been depressed an average of 26 years over their lifetimes. Their current episode had lasted more than 4 years on average, with 2 out of 3 in episodes lasting 2 years or more, despite an average of 4 adequate treatments.<sup>1</sup>

After a year in this study, the people with long-standing depression had rates of response (getting better) and remission (getting well) similar to rates for the entire study group.<sup>2</sup>

About 3 out of 10 of the people with long-lasting depression improved significantly with VNS Therapy, and 1 in 7 were depression-free (compared to 1 in 6 for the VNS Therapy group as a whole).<sup>1,2</sup>

As the chart shows, these rates of improvement were more than double those for a similar group of people who received standard antidepressant treatments but not VNS Therapy.



**Connections: a VNS Therapy resource program for you**

- Brochures
- Live phone conferences—VNS Therapy Phone Facts Sessions
  - Hear from a patient about his or her experience with VNS Therapy
  - Listen to a psychiatrist experienced with VNS Therapy
  - Tuesdays, June 5 and 19, July 10 and 17
  - 7:00 PM Central Time
  - Call TOLL-FREE 1-866-598-9336
- Nurse case managers who can answer your questions about VNS Therapy and help with insurance benefits verification
- For more information, call **1-877-NOW-4VNS** (1-877-669-4867) or visit [www.VNSTherapy.com](http://www.VNSTherapy.com)

**Timely tips for those who toss and turn**

Insomnia is a common symptom of depression. But there are techniques that may help you sleep better. A few tips from the National Institutes of Health<sup>4</sup>:

- Stick to a sleep schedule—even on weekends
- Exercise during the day (preferably outside), but not close to bedtime
- Avoid caffeine and nicotine. The stimulation can take 8 hours to wear off completely
- No nightcaps or big, late meals. Alcohol, a full bladder, or indigestion can interrupt your sleep
- No naps after 3 pm or longer than an hour
- Relax before bed. Try hot baths or quiet music
- Check your environment. Is it quiet, dark, comfortable, and cool enough?
- Don't lie in bed awake wondering why you're not asleep. Get up and do something relaxing until you feel sleepy

**References:** **1.** Rush AJ, Sackeim HA, Marangell LB, et al. Effects of 12 months of vagus nerve stimulation in treatment-resistant depression: a naturalistic study. *Biol Psychiatry*. 2005;58:355-363. **2.** Data on file. Cyberonics, Inc.; Houston, Tex. **3.** George MS, Rush AJ, Marangell LB, et al. A one-year comparison of vagus nerve stimulation with treatment as usual for treatment-resistant depression. *Biol Psychiatry*. 2005;58:364-373. **4.** National Heart, Lung, and Blood Institute. In Brief: Your Guide to Healthy Sleep. NIH Publication No. 06-5800. April 2006. Available at [www.nhlbi.nih.gov/health/public/sleep/index.htm](http://www.nhlbi.nih.gov/health/public/sleep/index.htm). Accessed April 19, 2007.

## SAFETY INFORMATION FOR THE VNS THERAPY™ SYSTEM\*

### INTENDED USE/INDICATIONS – UNITED STATES

The VNS Therapy System is indicated for the adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments.

### CONTRAINDICATIONS

The VNS Therapy System cannot be used in patients after a bilateral or left cervical vagotomy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with the VNS Therapy System. Diagnostic ultrasound is not included in this contraindication. Injury or damage can occur during diathermy treatment whether your VNS Therapy System is turned "ON" or "OFF".

### WARNINGS

This device is a permanent implant. It is only to be used in patients with severe depression who are unresponsive to standard psychiatric management. It should only be prescribed and monitored by physicians who have specific training and expertise in the management of treatment-resistant depression and the use of this device. It should only be implanted by physicians who are trained in surgery of the carotid sheath and have received specific training in the implantation of this device.

Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy System *Physician's Manual*, including information that VNS Therapy has not been determined to be a cure for depression. Patients being treated with adjunctive VNS Therapy should be observed closely for clinical worsening and suicidality, especially at the time of VNS Therapy stimulation parameter changes or drug or drug dose changes.

The safety and efficacy of the VNS Therapy System have not been established for uses outside the approved indications for use. Device malfunction could cause painful stimulation or direct current stimulation. Device removal requires an additional surgical procedure. Do not manipulate the Pulse Generator and Lead through the skin.

Patients who have pre-existing swallowing, cardiac, or respiratory difficulties (including, but not limited to, obstructive sleep apnea and chronic pulmonary disease) should discuss with their physicians whether VNS Therapy is appropriate for them since there is the possibility that stimulation might worsen their condition. Patients with the VNS Therapy System or any part of the VNS Therapy System implanted should not have full body MRI.

### PRECAUTIONS

The safety and efficacy of the VNS Therapy System have not been established for use during pregnancy. Patients who smoke may have an increased risk of laryngeal irritation.

### ADVERSE EVENTS

The most commonly reported ( $\geq 10\%$ ) side effects from stimulation included hoarseness, increased cough, neck pain, dyspnea (shortness of breath), dysphagia (difficulty swallowing), paresthesia (prickling feeling in the skin), and laryngismus (sore throat). The most commonly reported ( $\geq 10\%$ ) side effects from the implant procedure included incision pain, hoarseness, incision site reaction, device site pain, device site reaction, pharyngitis (sore throat), dysphagia, and hypesthesia (numbness).

\*THE INFORMATION CONTAINED IN THIS SUMMARY REPRESENTS PARTIAL EXCERPTS OF IMPORTANT PRESCRIBING INFORMATION TAKEN FROM THE PRODUCT LABELING. THE INFORMATION IS NOT INTENDED TO SERVE AS A SUBSTITUTE FOR A COMPLETE AND THOROUGH UNDERSTANDING OF THE VNS THERAPY SYSTEM, NOR DOES THIS INFORMATION REPRESENT FULL DISCLOSURE OF ALL PERTINENT INFORMATION CONCERNING THE USE OF THIS PRODUCT. (CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.)



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