

# Partner's Involvement Helps Adolescent Mothers

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SAN FRANCISCO — A study of adolescent mothers revealed that frequent contact with the father of their baby was associated with several beneficial effects, including improved maternal mental health and less endorsement of physical punishment for the child, Dr. Lee Savio Beers reported in a poster at the annual meeting of the Pediatric Academic Societies.

The study involved 138 mothers under the age of 20 years whose children were younger than 12 months old, said Dr. Beers of Children's National Medical Center, Washington, D.C., who conducted the study with Amy Lewin, Psy.D., and several other colleagues.

The women came from an urban population, and 94% were African American. They were questioned about the father's involvement in parenting the child, and they completed several standardized in-

struments intended to measure, for example, their mental health and level of self-esteem.

Only the 130 mothers who were 16-19 years old were asked about the age of the father. Eighteen percent of these fathers were age 17 or younger, 30% were 18-21, and the rest were 22 years old or older. Legal concerns prevented the investigators from asking younger mothers about the age of their child's father.

Overall, 52% of the fathers had com-

pleted high school, 30% were currently in school, 43% were employed, and 29% had children with other mothers.

The mothers reported a large amount of paternal contact with the babies; 62% of the mothers reported contact several times a week or more, 25% reported contact 1-8 times per month, and 14% reported rare contact or none at all, Dr. Beers said.

Sixty-one percent of mothers reported that they were satisfied with the level of paternal contact, 27% said that the contact was not frequent enough, and 12% said that their contact with the father was too frequent.

Although 75% of the mothers wanted the fathers to have frequent contact with the baby during the next 12 months, they had lower expectations for caregiving. Only 63% expected the fathers to feed the

## Brief Summary<sup>1</sup> of Safety Information for the VNS Therapy<sup>TM</sup> System (Depression Indication) July 2005

### 1. INTENDED USE / INDICATIONS: DEPRESSION (USA)

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.

### 2. 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 a VNS Therapy System. Diagnostic ultrasound is not included in this contraindication.

### 3. WARNINGS

Physicians should inform patients about all potential risks and adverse events discussed in the *Physician's Manual (Depression)*. This document is not intended to serve as a substitute for the complete *Physician's Manual (Depression)*.

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 warn patients that VNS Therapy has not been determined to be a cure for depression.

The safety and efficacy of the VNS Therapy System have not been established for uses not covered in the "Intended Use/Indications" section of the *Physician's Manual (Depression and Epilepsy)*.

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 effectiveness of the VNS Therapy System in patients with predisposed dysfunction of cardiac conduction systems (re-entry pathway) have not been established. Postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. Post-implant electrocardiograms and Holter monitoring are recommended if clinically indicated.

It is important to follow recommended implantation procedures and intraoperative product testing described in the *Physician's Manual (Depression)*. During the intraoperative System Diagnostics (Lead Test), infrequent incidents of bradycardia and/or asystole have occurred. If asystole, severe bradycardia (heart rate <40 bpm), or a clinically significant change in heart rate is encountered during a System Diagnostics or during initiation of stimulation, physicians should be prepared to follow guidelines consistent with Advanced Cardiac Life Support (ACLS).

Difficulty swallowing (dysphagia) may occur with active stimulation, and aspiration may result from the increased swallowing difficulties. Patients with pre-existing swallowing difficulties are at greater risk for aspiration.

Shortness of breath (dyspnea) may occur with active VNS Therapy. Any patient with underlying pulmonary disease or insufficiency such as chronic obstructive pulmonary disease or asthma may be at increased risk for dyspnea.

Patients with obstructive sleep apnea (OSA) may have an increase in apneic events during stimulation. Lowering stimulus frequency or prolonging "OFF" time may prevent exacerbation of OSA. Vagus nerve stimulation may also cause new onset sleep apnea in patients who have not previously been diagnosed with this disorder.

Device malfunction could cause painful stimulation or direct current stimulation. Either event could cause nerve damage. Patients should be instructed to use the Magnet to stop stimulation if they suspect a malfunction, and then to contact their physician immediately for further evaluation.

Patients with the VNS Therapy System or any part of the VNS Therapy System implanted should not have full body MRI.

Use of the Magnet to activate stimulation is not recommended for patients with depression.

Excessive stimulation at an excess duty cycle has resulted in degenerative nerve damage in laboratory animals.

Patients who manipulate the Pulse Generator and Lead through the skin may damage or disconnect the Lead from the Pulse Generator and/or possibly cause damage to the vagus nerve.

### 4. PRECAUTIONS

Physicians should inform patients about all potential risks and adverse events discussed in the *Physician's Manual (Depression)*.

Prescribing physicians should be experienced in the diagnosis and treatment of depression and should be familiar with the programming and use of the VNS Therapy System.

Physicians who implant the VNS Therapy System should be experienced performing surgery in the carotid sheath; physicians should be familiar with vagus nerve anatomy, particularly the cardiac branches; and they should be trained in the surgical technique relating to the implantation of the VNS Therapy System.



The safety and effectiveness of the VNS Therapy System have not been established for use during pregnancy. VNS Therapy should be used during pregnancy only if clearly needed.

The VNS Therapy System is indicated for use only in stimulating the left vagus nerve in the neck area inside the carotid sheath.

The VNS Therapy System is indicated for use only in stimulating the left vagus nerve below where the superior and inferior cervical cardiac branches separate from the vagus nerve.

It is important to follow infection control procedures. Infections related to any implanted device are difficult to treat and may require that the device be explanted. The patient should be given antibiotics preoperatively. The surgeon should ensure that all instruments are sterile prior to the procedure.

The VNS Therapy System may affect the operation of other implanted devices, such as cardiac pacemakers and implanted defibrillators. Possible effects include sensing problems and inappropriate device responses. If the patient requires concurrent implantable pacemaker, defibrillatory therapy or other types of stimulators, careful programming of each system may be necessary to optimize the patient's benefit from each device.

Reversal of Lead polarity has been associated with an increased chance of bradycardia in animal studies. It is important that the electrodes are attached to the left vagus nerve in the correct orientation. It is also important to make sure that Leads with dual connector pins are correctly inserted (white marker band/serial number to + connection) into the Lead receptacles.

The patient can use a neck brace for the first week to help ensure proper Lead stabilization.

Do not program the VNS Therapy System to an "ON" or periodic stimulation treatment for at least 14 days after the initial or replacement implantation.

Do not use frequencies of 5 Hz or below for long-term stimulation.

Resetting the Pulse Generator turns the device OFF (output current = 0.0 mA), and all device history information is lost. Patients who smoke may have an increase risk of laryngeal irritation.

### 5. ENVIRONMENTAL AND MEDICAL THERAPY HAZARDS

Patients should exercise reasonable caution in avoiding devices that generate a strong electric or magnetic field. If a Pulse Generator ceases operation while in the presence of electromagnetic interference (EMI), moving away from the source may allow it to return to its normal mode of operation. VNS Therapy System operation should always be checked by performing device diagnostics after any of the procedures mentioned in the *Physician's Manual (Depression)*.

For clear imaging, patients may need to be specially positioned for mammography procedures because of the location of the Pulse Generator in the chest.

Therapeutic radiation may damage the Pulse Generator's circuitry, although no testing has been done to date and no definite information on radiation effects is available. Sources of such radiation include therapeutic radiation, cobalt machines, and linear accelerators. The radiation effect is cumulative, with the total dosage determining the extent of damage. The effects of exposure to such radiation can range from a temporary disturbance to permanent damage, and may not be detectable immediately.

External defibrillation may damage the Pulse Generator.

Use of electrocautery (electrocautery or radio frequency (RF) ablation devices) may damage the Pulse Generator.

Magnetic resonance imaging (MRI) should not be performed with a magnetic resonance body coil in the transmit mode. The heat induced in the Lead by an MRI body scan can cause injury. If an MRI should be done, use only a transmit-and-receive type of head coil. MRI compatibility was demonstrated using a 1.5T General Electric Sigma Imager with a Model 100 only. When other MRI systems are used, adverse events may occur because of different magnetic field distributions. Consider other imaging modalities when appropriate.

Procedures in which the radiofrequency (RF) is transmitted by a body coil should not be done on a patient who has the VNS Therapy System. Thus, protocols must not be used which utilize local coils that are RF-receive only, with RF-transmit performed by the body coil. Note that some RF head coils are receive only, and that most other local coils, such as knee and spinal coils, are also RF-receive only. These coils must not be used in patients with the VNS Therapy System.

Extracorporeal shockwave lithotripsy may damage the Pulse Generator. If therapeutic ultrasound is required, avoid positioning the area of the body where the Pulse Generator is implanted in the water bath or in any other position that would expose it to ultrasound therapy. If that positioning cannot be avoided, program the Pulse Generator output to 0 mA for the treatment, and then after therapy, reprogram the Pulse Generator to the original parameters.

If the patient receives medical treatment for which electric current is passed through the body (such as from a TENS unit), either the Pulse Generator output should be set to 0 mA or function of the Pulse Generator should be monitored during initial stages of treatment.

Routine therapeutic ultrasound could damage the Pulse Generator and may be inadvertently concentrated by the device, causing harm to the patient.

For information related to home occupational environments, cellular phones, other environmental hazards, other devices, and ECG monitors, please refer to the *Physician's Manual (Depression)* for complete information.

### 6. ADVERSE EVENTS

Implant-related adverse events reported during the pivotal study in ≥5% of patients are listed in order of decreasing occurrence: incision pain, device alteration, incision site reaction, device site pain, device site reaction, pharyngitis, dysphagia, hypesthesia, dyspnea, nausea, headache, neck pain, pain, paresthesia, and cough increased.

Stimulation-related adverse events reported during the acute sham-controlled study by ≥5% of VNS Therapy-treated patients are listed in order of decreasing occurrence: voice alteration, cough increased, dyspnea, neck pain, dysphagia, laryngismus, paresthesia, pharyngitis, nausea, and incision pain.

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Mothers with daily contact with the father had less depression and higher self-esteem.

DR. BEERS

baby, 43% expected the fathers to change the diapers, and 35% expected the fathers to attend the baby's medical appointments, she said.

Fifty-two percent of the mothers reported being in a romantic relationship with the father of their baby; 85% said that these men treated them with respect, and 24% reported having arguments with the men often or very often, Dr. Beers reported at the meeting, sponsored by the American Pediatric Society, the Society for Pediatric Research, the Ambulatory Pediatric Association, and the American Academy of Pediatrics.

Daily contact with the father clearly had beneficial effects. Compared with mothers who had less-than-daily contact with the father, mothers with daily contact had significantly lower levels of depression, had significantly higher levels of self-esteem, and were significantly less likely to say that they endorsed physical punishment of their child.

The investigators found several outcomes among mothers satisfied with the level of paternal contact that were not considered positive in adolescent parents: these mothers were significantly less likely to live with their own mothers or grandmothers, significantly more likely to have more than one child, and were significantly less likely to be in school.

<sup>1</sup>The information contained in this Brief Summary for Physicians represents partial excerpts of important prescribing information taken from the *Physician's Manual (Depression)*. (Copies of *VNS Therapy Physician's and Patient's Manuals* are posted at [www.VNSTherapy.com/manuals](http://www.VNSTherapy.com/manuals)). The information is not intended to serve as a substitute for a complete and thorough understanding of the material presented in all of the *Physician's Manuals* for the VNS Therapy System and its component parts, nor does this information represent full disclosure of all pertinent information concerning the use of this product, potential safety complications, or efficacy outcomes.

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NEXT ISSUE

Medicinal Herbs

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