North Pacific Epilepsy Research Center

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Vagal Nerve Stimulation

a new therapy for intractable epilepsy

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November, 2001

Vagal nerve stimulation (VNS), is a technique in which electrical stimulation of the left vagal nerve in the neck is used to reduce the frequency and severity of seizures in persons with epilepsy. This is similar to the practice of implanting a cardiac pacemaker. The VNS consists of a generator, a small disc shaped device approximately 2 inches in diameter and 1/2 an inch thick, which is implanted under the skin of the left chest. This provides electrical power via an insulated wire which contains two spring shaped electrodes that are wrapped around the left vagal nerve in the neck. The generator is powered by a battery and while like a cardiac pacemaker it does not stimulate the brain directly but by stimulating the vagus nerve electrical discharges are sent upward into a wide variety of areas in brain.

The device is manufactured by the Cyberonics Corporation of Houston, Texas. Approximately 13,000 persons with epilepsy have had VNS implantation. The implantation is a surgical procedure requiring general anesthesia and takes about one hour. Patients usually go home the same day the VNS is implanted.

After implantation the generator must be programmed to deliver a precise amount of electrical stimulation intermittently. This is done using a computer and a hand held "wand". The wand is placed over the generator and programming takes about 15 minutes. The VNS output is gradually increased by reprogramming monthly over 4-5 months. This is done in a doctor's office.

The generator sends pulses of electricity usually for 30 seconds every five minutes. Though most persons have no awareness of the generators signal some persons develop hoarseness of difficulty swallowing while the generator is "on". This can often be reduced by adjusting the generator's program.

How the VNS works

In 1938 Bailey and Bremmer discovered that electrical stimulation of the vagal nerve desynchronized the EEG in cats. Subsequent studies demonstrated that vagal nerve stimulation (VNS), could decrease interictal epileptiform discharges. Further studies in humans followed. Five clinical studies demonstrating the effectiveness of the VNS lead to FDA approval in 1997.

How the VNS actually prevents seizures is not precisely known. It is clear that it prevents the hypersynchronization of neuronal activity seen in partial and generalized seizures. VNS increases the concentration of GABA (an inhibitory neurotransmitter) in cerebral spinal fluid. VNS also increases regional cerebral blood flow in the cerebellum, thalamus, insula and frontal lobes. It decreases blood flow to the amygdala, hippocampus and cingulate gyrus.

Benefits of VNS

The VNS takes some time to work. Initial effects are usually seen by 3 months. Persons using VNS will still require antiepilepsy medication (AED). They will however generally see fewer and less severe seizures. This table reviews the amount of improvement seen in persons with VNS.

# months of VNS	**Improvement**	**>50% reduction in seizures**	**>75% reduction in seizures**	**Sz. free**
3	20 %	23 %	16 %	---
9	---	---	---	0.5%
12	35 %	37 %	20 %	---
15	---	---	---	2.4 %
24	44 %	43 %	---	---
21	---	---	---	5.3 %
36	44 %	43 %	---	----

Disadvantages of VNS

Most persons cannot tell when the generator is turned on. Some persons do have side effects from the device, typically during the 30 second "on" time which occurs every 5 minutes. There does not appear to be any effect of the VNS on the heart. Over 250 patients were studied with continuous cardiac monitoring and no abnormalities were found. Rarely during implantation when the device is first turned on the heart may stop for 10-20 seconds. This has been seen in 6 out of 5,000 cases (1.2 %). All persons were revived and had no long term effects. Three of the 6 patients went on to have the VNS implanted and have had no adverse effects.

There have been 11 pregnancies in women using the VNS. Eight had normal children. Two women choose to have elective abortions in one of these the fetus was malformed probably from the AED the woman was also taking. One woman had a spontaneous abortion (miscarriage).

Cellular telephones, airport metal detectors, and microwave ovens do not effect the VNS.

This table demonstrates the most common side effects from VNS.

Side effect	**3**	**12**	**24**	**36 months**
Hoarseness	60 %	35 %	21 %	21 %
Cough	29 %	8 %	12 %	8 %
Paresthesias	19 %	6 %	4 %	3 %
Dyspnea	2 %	2 %	0 %	3 %

Criteria for having a VNS implanted

VNS is suggested for persons whose seizures are not controlled after they have tried at least 3 AED. Most studies have been performed on persons with partial seizures, but there has been some success with persons with generalized seizures as well. It can be used in persons who have had unsuccessful epilepsy surgery. Children as young as 4 years of age and older persons as old as 83 years have been implanted.

VNS should not be used in persons with non epileptic events or patients with psychoses, severe asthma, or severe heart disease particularly arrhythmias. Persons with cardiac pacemakers have successfully had VNS implanted.

The steps for VNS implantation

First confirm the diagnosis of epilepsy.

Determine that the seizures really are uncontrolled, and that adequate trials of at least 3 AED have occurred.

The risks and benefits of implantation of the VNS must be understood.

The patient must realize that VNS is not a substitute for medication, that complete seizure control is not a realistic goal, and be willing to come for follow up visits.

A consultation with the surgeon (neurosurgeon, Vascular surgeon or ENT surgeon) who will implant the device should occur before surgery.

Surgery is scheduled.

Outpatient visits are scheduled.

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