Harnessing the Power of the BODY'S ELECTRICAL SYSTEM

Frank Amato, CEO of electroCore, talks about how vagus nerve stimulation can be used for the preventive treatment of cluster headache and for the relief of pain associated with migraine and episodic cluster headache.


Frank Amato

Our nervous system interacts with a variety of different things in our bodies, including the immune system, using electrical signals. The vagus nerve, in particular, is the longest cranial nerve in the body, bringing information from visceral organs to the brain. The vagus nerve has a number of branching nerves that go to the heart, lungs, voice box, stomach, ears, and other organs. As a sensory nerve that assesses the condition of these organs, it acts as the communication vehicle between the brain and the body.

Stimulating the vagus nerve affects many important autonomic functions in the brain and in the body, including neurotransmitter levels, inflammation levels, and metabolism. Bioelectronic medicine — using technology to modulate electrical activity within the body's nervous system — is a relatively new approach to treating disease, especially when the therapy is non-invasive or taken out of the body.

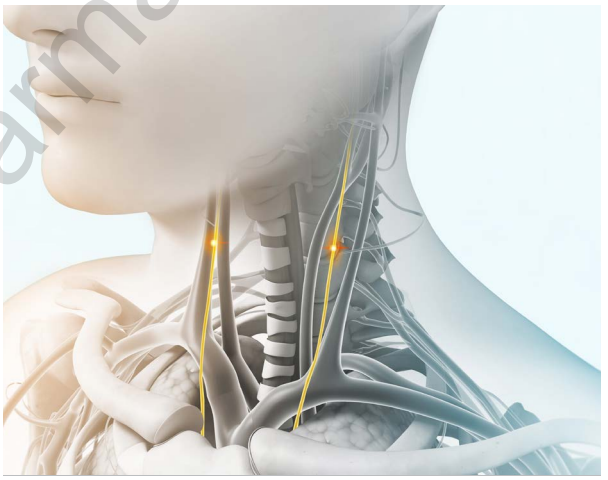
Implanted vagus nerve stimulation was approved in the 1990s initially for treating patients with epilepsy. When activated, the device sends electrical signals along the vagus nerve to the brainstem, which then sends signals to certain areas in the brain. But such therapies require surgery and are often expensive.

Now, electroCore has developed and launched a hand-held, non-invasive vagus nerve stimulator (nVNS) therapy that has the ability to administer a painless, mild electrical pulse through the skin to either the right or the left branches of the vagus nerve in the neck.

Designed as a portable, easy-to-use therapy, gammaCore Sapphire can be self-administered by patients without the potential side effects associated with commonly prescribed medicines. When placed on a patient's neck over the vagus nerve, gammaCore stimulates the nerve's afferent fibers, which may lead to a reduction or prevention of pain.

In November, the product received its third FDA clearance, for the adjunctive use for the prevention of cluster headache in adult patients. This is the first and only product FDA has cleared for the prevention of cluster headache. The therapy is also approved for the acute treatment of pain associated with episodic cluster headache and migraine headache in adult patients.

"We believe there is an opportunity to transform pain management by providing a safe, non-addictive, non-pharmacologic solution that's delivered comfortably through the skin," says Frank Amato, CEO of electroCore. "We figured out how to get a signal across the skin painlessly to restore the brain's natural biochemistry and neurological function."


electroCore has developed gammaCore, a non-invasive vagus nerve stimulator indicated for adjunctive use for the preventive treatment of cluster headache and for the relief of pain associated with migraine and episodic cluster headache.

electroCore's technology modulates electrical activity within the body's nervous system. "Our therapy gets a nerve to fire or cause an evoked potential," Mr. Amato says. "That evoked potential causes the nerve to fire back into the brainstem increasing inhibitory neurotransmitters, specifically GABA, norepinephrine, and serotonin. These three inhibitory nerve transmitters balance out any excitability that the brain experiences from excitatory neurotransmitters such as glutamate. These neurotransmitters are drug classes that the pharmaceutical industry has been modulating for the better part of the past 50 years."

Mr. Amato says gammaCore Sapphire has an adverse event profile as listed by the FDA that is mild and transient, and occurs during the use of the therapy. In other words, if a patient has any problem with the therapy, he or she just pulls it away from their neck, as opposed to having to inject, inhale, or ingest a chemical or a biologic to achieve a therapeutic benefit.

"There is an afferent effect to the technology," Mr. Amato says. "When the vagus nerve is stimulated, there are signals that go to the brain stem. There's also an efferent effect where the signal goes down and into the body. The efferent signal connects from the vagus nerve to the splenic nerve, and it is believed to have a profound anti-inflammatory effect."

According to electroCore, more than 15,000 prescriptions were written for gammaCore in 2018. gammaCore Sapphire, the next-generation, smaller version of the device, was released in August 2018.

electroCore is actively engaging with more than 50 national and regional commercial insurance payers in the United States with the goal of securing reimbursement coverage as a pharmacy or medical benefit.

The company continues to conduct research on gammaCore, including clinical studies to support an FDA application for the preventive treatment of migraine. electroCore also is conducting preclinical testing for treating rheumatoid arthritis and Sjogren's syndrome, an inflammatory disease that can affect many different parts of the body, but most often affects the tear and saliva glands.

After raising more than initial an $30 million in funding, electroCore announced in March 2013 a first closing on a Series A financing led by Merck Global Health Innovation Fund and Core Ventures, which raised $55 million. electroCore announced an initial public offering in June 2018. PV

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