Noninvasive VNS Device Emerges from Europe

by Warren Grill, senior technical editor

Vagus nerve stimulation for the treatment of medically refractory epilepsy—about one third of cases—was pioneered by Cyberonics, Inc., and over 60,000 patients have received implants worldwide. Now, Cerbomed, a private medical device company in Erlangen, Germany, is pursuing a noninvasive approach to treating epilepsy. The company was founded in 2005 to develop transcutaneous stimulation of the vagus nerve to treat neurological disorders, and has received a CE mark for the NEMOS transcutaneous stimulation system, which includes an earplug-like electrode to interface with the concha of the outer ear and a handheld battery-powered electrical stimulator.

The auricular branch of the vagus nerve innervates the concha of the ear and is located directly under the skin, making it a suitable target for transcutaneous stimulation. Earlier work demonstrated that transcutaneous VNS evoked patterns of cerebral activation, as determined by functional magnetic resonance imaging, that were similar to those evoked by direct VNS.

Further, preclinical studies in rats indicated that transcutaneous and direct VNS were similarly effective at reducing pentylenetrazole-induced seizures. Thirty seconds of stimulation at 20 Hz suppressed seizures for approximately 15 minutes with both stimulation modalities.

The company reported the results of a prospective pilot clinical study at the 10th World Congress of the International Neuromodulation Society held in London in May. Seven patients with drug-resistant epilepsy were enrolled at the University Hospital Erlangen. Patients used transcutaneous vagus nerve stimulation for approximately three hours per day for nine months. Five patients showed a reduction in seizure frequency. The director of the clinical trial judged transcutaneous vagus nerve stimulation "as a safe and compatible method for long-term application," and stated that it represents a possible therapy alternative for patients with hard to treat epilepsies.

"The result of the pilot study is another important milestone for our company. It motivates us to carry out a worldwide, multi-center study for t-VNS therapy", concluded Jens Ellrich, chief medical officer at Cerbomed.

In addition to this prospective pilot study to evaluate the safety, tolerance, and clinical performance in treating epilepsy, Cerbomed is also pursuing clinical studies in tinnitus, schizophrenia, and depression. As well, their studies in treating pain were presented at INS and suggested reduced pain sensitivity in normal volunteers during transcutaneous vagus nerve stimulation.

Rather than stealing market share, this noninvasive approach to VNS may actually lead to growth in the implanted VNS market. Noninvasive stimulation may enable identification of responders in advance of implantation, and thereby enable implanted VNS to capture less severe patients, who otherwise might not be considered for surgery. Further, noninvasive VNS is already enabling testing in new indications, which, if they require permanent stimulation for long term treatment, may be more suited to a permanent implant than a transcutaneous approach.

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