

Wearable Nerve Stimulator Improves Chronic Pain

Pauline Anderson | September 17, 2015

LAS VEGAS — A noninvasive wearable nerve stimulator improves pain to the point of needing less analgesia in patients with neuropathy, arthritis, and other common forms of chronic pain, a new study shows.

"Our data suggest, and this is mimicked anecdotally, that this device works for about eight out of 10 people," said Shai Gozani, MD, PhD, president and chief executive officer, NeuroMetrix, manufacturer of the device.

Dr Gozani presented the company-funded study here at PAINWeek 2015. The device (*Quell*, NeuroMetrix) was approved for use by the US Food and Drug Administration in 2014.

Endogenous Opioids

The stimulator, inserted into a slim, lightweight band and worn on the upper calf, stimulates sensory nerves, which carry neural pulses to the brain. The pulses trigger release of endogenous opioids within the spinal cord.



Dr Shai Gozani

"It elevates endogenous opioids, so it's actually operating through some of the same pathways as opioids," explained Dr Gozani. "But because it's all endogenous, it's very precise and doesn't have some of the negative side effects of prescription opioids such as addiction or euphoria; this is purely for pain control."

The class 2 medical device is the first of its kind and recently became available over the counter.

Based on TENS

Although the *Quell* device is relatively new, it uses the concept of transcutaneous electrical nerve stimulation (TENS), which has been around since the early 1970s. "We wanted to put it into a format that someone could wear for chronic pain relief: for an hour before going to bed, for 8 hours a day, overnight, or wear it continuously," said Dr Gozani.

The device is calibrated to the individual patient's sensory threshold and automatically sets stimulation intensity to a therapeutic level. After calibration, each 60-minute therapy session starts automatically every other hour.

The system brings pain relief in as little as 15 minutes, according to the company. It seems to work well for musculoskeletal and neuropathic pain, but because the device blocks pain signals at the level of the brain stem, it does not ease headache pain such as migraines, said Dr Gozani.

As it is worn on the upper calf, it is "convenient and accessible and discreet," said Dr Gozani. "You can wear it under clothing, under a dress or pants."

There is now also a smartphone app for users to track their therapy.

Study Results

The new study of the device included 88 chronic pain patients at least 40 years old (mean age, 55.7 years), which represented 67.7% of the number initially enrolled. Most (61.4%) patients had arthritis, with the next most common pain conditions being sciatica, fibromyalgia, and neuropathy.

Participants were asked to use the device at home on a daily basis for 60 days to manage pain. They then completed

an online questionnaire.

The researchers found that 80.7% of subjects reported either much improved or improved chronic pain, as measured by the five-point Patient Global Impression of Change scale (95% confidence interval, 72.4% - 88.9%).

About two thirds of patients reported a reduction in use of pain medication: 31.8% said it was decreased a lot, and 35.2% said it was reduced a little.

Limitations of the study were that it was open label and did not determine the reason for lack of response to the follow-up questionnaire, and device utilization was self-reported, rather than obtained from electronic logs.

As with any pain therapy, the device does not work for everyone, said Dr Gozani. "I feel like it works broadly, but in any given category, not everyone is going to benefit."

The device costs \$250. Each electrode lasts about 100 hours, so with typical use, it needs replacing every 2 weeks, at a cost of about a dollar a day.

It is contraindicated with pacemakers and defibrillators.

Dr Gozani founded NeuroMetrix in 1996 as a spinoff from the Harvard-MIT Division of Health Sciences and Technology.

Medscape Medical News asked Mathew M. John, DPM, a podiatric surgeon and medical director, Atlanta Center for Foot & Ankle Surgery, Marietta, Georgia, to comment on the device.

He said he has used it on patients with chronic foot pain who have failed multiple traditional treatments.

"I find that patients are more compliant, more motivated in using Quell before considering other invasive surgery options," Dr John said. "Quell has been a tremendous advantage in my practice by allowing me to offer an advanced treatment modality with little to no disadvantages or side effects."

The study was funded by NeuroMetrix. Dr Gozani is chief executive officer of NeuroMetrix. Dr John has disclosed no relevant financial relationships.

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