

Nerve stimulation therapy alleviates pain for chronic headache

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A novel therapy using a miniature nerve stimulator instead of medication for the treatment of profoundly disabling headache disorders improved the experience of pain by 80-95 percent, according to a new study from the University of California, San Francisco and the National Hospital for Neurology and Neurosurgery in London.

The findings give doctors the promise of a non-drug treatment option for pain sufferers unable to tolerate indometacin, the standard medication known to cause stomach bleeding in some patients. Findings are reported online at www.thelancet.com and also will appear in the November 2008 issue of "*Lancet Neurology*."

Up to 35 million Americans suffer migraine and other forms of headache, according to the American Academy of Neurology.

"We need a range of treatments to offer patients whose lives are taken over by debilitating headaches," said Peter J. Goadsby, MD, PhD, lead author, neurologist and director of the UCSF Headache Center. "It's quite exciting to think about how technology will advance in the next five years to provide remarkable devices for the treatment of headache. Preventive approaches like these will completely change the landscape of headache treatment."

The device, called a bion, is a rechargeable battery-powered electrode, similar in size to a matchstick. When implanted near the occipital nerve in the back of the neck, it alleviates pain by generating pulses that the

nerve receives. The bion can be turned on or off via an external wireless remote control. Previous versions of the bion have been used in pain management for osteoarthritis and in the treatment of dislocated joints for patients recovering from stroke.

The study measured the effectiveness of nerve stimulation in six patients aged 37 to 64 with hemicrania continua, a rare headache disorder defined by the International Headache Society as a form of chronic daily headache in which patients have 15 days or more of headache per month.

At the beginning of the study, participants underwent a minimally invasive surgery to have the bion implanted at the occipital nerve. Each participant then received continuous stimulation of the nerve for the first three months. The device was switched off for the fourth month, ensuring that patients did not receive stimulation of the occipital nerve during that time, and switched on again at month five.

Switching off the bion enabled researchers to measure whether the device – rather than the placebo affect – was responsible for pain modulation.

To test long-term safety and efficacy of nerve stimulation therapy, follow-up sessions with the patient, a researcher and a device technician occurred once per month for four months.

Patients kept diaries, at hourly intervals during waking hours, which included a pain severity scale ranging from 1 to 10 points. Participants shared their diaries with researchers after the fifth month.

Researchers found that within a range of six to 21 months after implantation of the bion, five of the six patients reported sufficient benefit to recommend the device to other patients with hemicrania

continua. Similar results were reported in 2007 by two other research teams studying patients with chronic cluster headaches.

At long-term follow-up, four of the six patients reported substantial pain improvement at a level of 80 to 95 percent, one patient saw a 30 percent improvement, and one patient reported that his pain worsened by 20 percent.

Overall, the research team found that participants not only improved with the bion therapy, but their pain worsened when the bion was switched off during the fourth month. In addition, diary submissions revealed an overall reduction in the pain score of five to eight points.

"The treatment of migraine and other chronic headache pain can be a considerable challenge to physicians. Not all patients can tolerate the appropriate medicines, and the side effects leave patients and doctors in a difficult position," Goadsby said.

"We have the opportunity to afford a huge change in quality of life for these patients. The bion was well tolerated, and neuromodulation is proving an effective and safe option, particularly in cases when patients have difficulty stomaching indomethacin."

The study is the first systemic use of the second generation of neurostimulators for the alleviation of primary headache, according to researchers. Occipital nerve stimulation is currently being studied for use in migraine treatment.

Source: University of California - San Francisco

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