Was longer treatment duration with noninvasive vagus nerve stimulation associated with a clinically significant reduction in headache days?

Prophylactic use of noninvasive vagus nerve stimulation (nVNS) was well-tolerated and resulted in a small numerical reduction in the number of chronic migraine headache days, according to the results of a small pilot study. However, the technique failed to significantly reduce the number of headache days that participants experienced compared to participants in a sham-controlled treatment arm.

“We assessed whether longer treatment duration was associated with clinically meaningful results, as previously reported in a study of neuromodulation in chronic migraine,” wrote researcher Stephen D. Silberstein, MD, of Jefferson Headache Center, Philadelphia, and colleagues in Neurology. “Participants originally randomized to nVNS and who continued open-label treatment for 6 months had a significant reduction from baseline in the number of headache days.”

According to the study, neuromodulation using vagus nerve stimulation is often conducted with an implanted device; however, the implants are associated with high risks and surgical costs, and have not been studied for migraine prevention. This study evaluated a patient-controlled, handheld, noninvasive stimulation device.

The study enrolled 59 participants with a mean headache frequency of 21.5 headache days per month. The participants were randomly assigned to nNVS or a sham treatment before the open-label phase of the study where all patients could receive nVNS. During the randomized phase, participants in both arms reported similar tolerability, with only mild to moderate adverse events. The most common adverse events were upper respiratory tract infection and gastrointestinal symptoms.

Participants assigned to nVNS had a mean change of -1.4 in headache days (from 20.8 to 19.4) compared with -0.2 for participants in the sham arm (from 22.3 to 22.0). After the randomization phase, 27 participants completed the open-label phase, 16 of whom were initially assigned to nVNS. Among these 16 participants, the mean change in headache days from baseline was -3.6 (P=0.02).

“Although self-selection bias is associated with the long-term findings, the continued reduction in headache days over the 6-month open label phase suggests that nVNS may offer a clinical benefit to patients with chronic migraine,” the researchers wrote. “Longer-term use of nVNS in treatment responders would be reflective of clinical practice.”

According to the researchers, larger studies with a longer treatment duration would be helpful to validate the use of nVNS in patients with chronic migraine.


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