Direct brain neurostimulation for partial onset seizures provides long-term benefit

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Piotr Olejniczak, MD, PhD, LSU Health New Orleans Professor of Neurology and Director of the Epilepsy Center, contributed to a study of the long-term effectiveness of the first direct brain responsive neurostimulator for partial onset, or focal, seizures that cannot be controlled with medication. The study found that responsive direct cortical stimulation reduces seizures and improves quality of life over an average of 5.4 years. The study is published in the February 24, 2015, issue of the journal, *Neurology*.

The results are part of the Long-Term Treatment (LTT) Study, an ongoing seven-year multicenter prospective open-label study to evaluate the long-term efficacy and safety of the RNS System. The technology, FDA-approved for adults with focal (in one part of the brain) seizures, continuously monitors electrical activity in the brain, detects patterns programmed by the physician and delivers brief pulses of stimulation to help prevent seizures from starting. Only after a comprehensive assessment of a patient's epilepsy and medical history, neurosurgeons implant the programmable neurostimulator under the scalp and place the lead or wires in the area of the brain where seizures begin.

A total of 256 participants were implanted with the neurostimulator and leads, and 230 of these participants enrolled in the LTT Study. A total of 191 participants continued to participate as of this data cutoff date, resulting in an accumulated experience of 1,389 patient implant years and 1,293 patient stimulation years. The median percent reduction in seizures was 44% at 1 year and 53% at 2 years postimplant, a significant

improvement over time. The median percent reduction in seizures was 60% at the beginning of year 3 and 66% at the beginning of year 6. The responder rates at the same time points were 58% and 59%, respectively.

Seizure frequency decreased in the majority of participants treated with responsive stimulation. Based on the most recent 3 months of available data for each participant (a last observation carried forward analysis for those with 3 complete months of data), 84% of participants (207/247) had some improvement, 60% (146/247) had a 50% or greater reduction (compared to 8% [19/247] with a 50% or greater increase), and 16% of participants (40/247) were seizure-free. Some participants had extended periods of seizure freedom. Over one-third (36.7%) of the 256 implanted participants had at least 1 seizure-free period of 3 months or longer, 23.0% had at least 1 seizure-free period of 6 months or longer, and 12.9% had at least 1 seizure-free period of 1 year or longer. No participants were seizure-free over the entire follow-up.

According to the Centers for Disease Control and Prevention, about 2.3 million people in the United States (about 1 in 100) have epilepsy. About 1 in 26 people will be diagnosed with epilepsy at some point in their lives. About 150,000 new cases of epilepsy will be diagnosed in the United States each year. While most people with epilepsy live a full life, the risk of early death is higher for some. Falls or other injuries resulting from seizures can be life-threatening. Uncontrolled focal epilepsy causes physical, psychological, social challenges as well.

The Institute of Medicine concluded that at least 30% of adults with partial onset seizures do not achieve seizure control with antiepileptic medications, and a similar percentage have significant medication-related side effects.

"Our St. Charles Avenue LSU Healthcare Network clinic has become an official programming site for the Responsive Neural Stimulator System,"

notes Dr. Olejniczak.

Provided by Louisiana State University