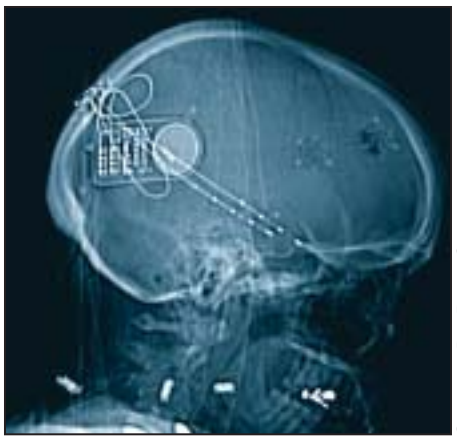
Device Promising in Uncontrolled Seizures



COURTESY DR. RYDER GWINN

The iPod-sized RNS System implanted in a patient's cranium is seen on x-ray.

BY DOUG BRUNK
San Diego Bureau

SAN DIEGO — The RNS System, an investigational device that delivers responsive stimulation to the brain of patients with uncontrolled seizures, shows promise in clinical trials, but the technical learning curve is steep, Dr. Ryder Gwinn said at the annual meeting of the Congress of Neurological Surgeons.

"Programming experience is growing but it's still not where we need to be," said Dr. Gwinn, director of surgical epilepsy at the Swedish Neuroscience Institute, Seattle. "I am very frequently changing parameters in order to reach seizure freedom. However, I believe that the system will become much easier to use as a result of the clinical trials currently underway."

Dr. Ryder disclosed he is a steering committee member for the devices' maker, NeuroPace Inc., but has not received consulting fees outside of the study budget. He has no personal financial interest in the company.

The RNS System is a fully implanted, microprocessor-controlled device that uses up to nine contacts for stimulation. About the size of an iPod, it detects electrographic patterns from intracranial electrodes and delivers up to five separate programmable therapies. It stores up to 32 minutes of electrocorticogram data that can be downloaded to a laptop at any time.

Benefits of the device include focal treatment that leaves functional neuronal circuits intact, Dr. Gwinn said. In addition, a decision to treat "can be made without significant concern for functional consequences, and it doesn't preclude later alternative treatments."

Concerns about the use of such technology include the fact that localization of focus could be critical to success. "Early seizure detection is important for contingent stimulation, and potentially abnormal tissue or aberrantly organized circuits would be left intact," he noted.

In a recent feasibility study, Dr. Gwinn and his associates at 11 centers used the RNS System in 65 patients aged 18-65 years who had simple or complex partial seizures.

Patients were eligible for the trial if they had failed treatment with a minimum of two antiepileptic drugs; had a minimum of four seizures per month for 3 months; and had an established region of epileptiform activity. The primary end points were safety and preliminary evidence of efficacy. Response was defined as seizure reduction by more than 50%.

Of the 65 patients implanted with the RNS System, 50 received stimulation, one patient had a device that was never turned on, and 14 patients were in a sham-stimulation group (therapy off).

After a mean 847 days of follow-up, the researchers observed a responder rate of 32% in patients with complex partial seizures, 63% in patients with generalized tonic-clonic seizures, and 26% in those with total, disabling seizures (simple partial motor seizures, complex partial seizures, and generalized tonic-clonic seizures combined).

As of June 5, 2007, there were 15 serious adverse events, including one case of focal status epilepticus, one case of erosion from the leads, and one case of tissue infection, all of which resolved. Other adverse events included one case each of increase in seizure severity, confusion, sensitivity to visual stimuli, and sudden unexplained death in epilepsy (SUDEP). None of these adverse events were thought to be definitively related to the use of the device.

The researchers concluded contingent stimulation appears to benefit patients with uncontrolled seizures. "More stimulation seems to be better, but early stimulation is often not enough to have an impact," Dr. Gwinn said. "No parameters so far can reliably eradicate seizures altogether."

Dr. Gwinn and his associates at 28 centers are currently enrolling patients aged 18-70 years in a similar but larger pivotal study. The recruitment goal is 240 patients.

For now, the therapy appears to be safe. "Stimulation has been applied to all lobes, including the medial temporal lobe," he said. ■