Implanted device predicts epilepsy seizures in humans

May 1 2013

For the first time, a small device implanted in the brain has accurately predicted the onset of seizures in some adults who have epilepsy that doesn't respond to drugs, according to a small proof-of-concept study published Online First in *The Lancet Neurology*.

"Knowing when a seizure might happen could dramatically improve the quality of life and independence of people with epilepsy and potentially allow them to avoid dangerous situations such as driving or swimming, or to take drugs to stop seizures before they start, rather than continuously as at present", explains lead author Mark Cook from the University of Melbourne in Australia.

The technology, developed by NeuroVista, is designed to detect abnormal electrical activity in the brain that precedes a seizure using electrodes implanted between the skull and brain surface which constantly monitor electrical activity (electroencephalography; EEG) data. The electrodes are connected to a second device implanted under the skin of the chest which transmits this information wirelessly to a hand-held device that calculates the probability of a seizure. Three coloured lights warn patients of the high (red), moderate (white), or low (blue) risk of an impending seizure.

More than 60 million people worldwide have epilepsy, 30–40% of these patients are unable get their seizures under control with existing treatments.

The Australian feasibility study included 15 people with focal epilepsy aged 20–62 years who experienced between two and 12 seizures per month and had not had their seizures controlled despite use of at least two anti-epileptic drugs.

During the first month after surgical implant, the system was set for detection only while EEG data containing a minimum of five seizures was collected and analysed to construct an individualised algorithm of seizure likelihood.

The researchers measured the system's performance, clinical effectiveness, and safety for 4 months after implant and 4 months following activation.

During the initial data collection, the system correctly predicted seizures with a "high warning" sensitivity greater than 65%, and worked to a level better than chance, in 11 of the 15 adults. In eight of the 11 patients who went on to have the device activated and to use the system for 4 months, sensitivity ranged from 56% to 100%.

The technology appears to be relatively safe, with a similar safety profile to other implanted devices such as deep brain stimulators for Parkinson's disease. Three patients experienced serious device-related adverse events, with two requiring the device to be removed.

Strikingly, the study also revealed substantial disparities between reported and detected events, with most participants greatly underestimating the number of their seizures. For example, one patient who reported having 11 seizures per month actually had 102. "Our findings have pronounced implications for trials of new epilepsy treatments which often rely on patient-reported events as the primary efficacy endpoint", write the authors.

Cook is optimistic that if the findings are replicated in larger, longer studies, this technology will improve management strategies including developing methods of preventing seizures using direct electrical stimulation or fast-acting drug therapies.

Writing in a linked Comment, Christian Elger and Florian Mormann from the University of Bonn Medical Centre in Germany say, "[These results] are a major milestone in epileptology [the study of epilepsy], showing for the first time (to our knowledge) that prospective seizure prediction is possible…[but] whether this performance is also sufficient for clinical application is unclear; this will depend on how well patients tolerate false alarms or missed seizures, and will ultimately need to be decided on an individual basis. Nevertheless, the presented results suggest that at least some patients would view the warning device as beneficial."

More information: www.thelancet.com/journals/lan … (13)70075-9/abstract

Provided by Lancet