Home Testing Devices Could Monitor Epilepsy Drug Levels, Reduce Clinical Visits

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Washington, D.C., December 9, 2013— Medications remain the mainstay of epilepsy treatment, and to date there are no FDA-approved devices that provide an accurate means of detection for generalized tonic-clonic seizures (GTCS), or convulsions, during activities of daily living. Two new studies presented at the American Epilepsy Society’s 67th Annual Meeting in Washington D.C. provide data that warrants the development of non-invasive devices with the capability to signal the onset of an epileptic seizure and could be crucial to optimal patient dosing.

Interim analysis that aims to validate a seizure detection software algorithm was presented to support the development of a non-invasive detection device with the ability to measure electromyography (EMG) signals (Poster 2.037 / Abstract 1750832). Patients in this study were asked to wear an arm-device that detected all GTCS within 30 seconds of arm motor action. Thirty-three patients with a history of seizures were enrolled in the study while in the hospital Epilepsy Monitoring Unit for routine EEG monitoring.

“Our study demonstrates the feasibility to detect generalized tonic-clonic seizures with an arm device analyzing muscle activity during daily living. We were able to capture the GTCS through analysis of EMG signals and confirmed these seizures using video-EEG (vEEG) recordings. The software algorithm was optimized using baseline measurements of maximum voluntary muscle contraction (MVC). In all but one instance that a GTCS was recorded by vEEG, it was also captured by EMG, proving the device to be over 95% sensitive in detecting GTCSs,” said Akos Szabo, MD, the lead researcher of the study.

The results determined that the seizure detection algorithm appeared superior to the other devices currently under investigation or currently commercialized. Only one false alarm was triggered during 1,400 hours of activities of normal living.

In a related study conducted by a research team at the University of Texas Houston, a study testing bio-nano-chips (BNCs) as a non-invasive, repeatable and adaptable alternative to serial serum antiepileptic drug measurements (Platform A.09 / Abstract 1750229). This study provides a report on progress towards developing a realistic saliva-based BNC system for two commonly used antiepileptic drugs – phenytoin (PHT) and phenobarbital (PHB). The purpose of this technology is to allow a patient or their caregiver to detect the level of antiepileptic drugs in their system and monitor their drug levels outside of their doctor’s office.
“These bio-nano-chips, or “labs on a chip” as we like to call them, are a new generation of compact, programmable chemical processors that will satisfy the urgent need for non-invasive, adaptable and cost effective alternatives to blood test,” said Giridhar P. Kalamangalam, MD.

The BNC calibration signals were robust and provided low reliable limits of detection, and compared favorably to the in-lab gold standards. Further work will aim to produce a practical point of care diagnostic, eventually a hand-held device the size of a credit card that will empower patients to monitor drug intake on their own.

Editor’s Note: Authors of these studies will be available at a press briefing at 1:30 pm (EST), Monday, December 9, in the onsite press room, Room 209A, Level 2 of the Walter E. Washington Convention Center. The call-in number for off-site journalists is 1-605-475-4000, passcode 521653#.

About Epilepsy
The epilepsies affect 50 million people worldwide, including three million in the United States. The disorder can have a single specific, well-defined cause, such as a head injury, or manifest as a syndrome with a complex of symptoms. It is the third most common neurological disorder after Alzheimer’s disease and stroke.

About the American Epilepsy Society (AES)
The American Epilepsy Society, based in West Hartford, Conn., seeks to advance and improve the treatment of epilepsy through the promotion of research and education for healthcare professionals. Society membership includes epileptologists and other medical and allied healthcare professionals, and scientists concerned with the care of people who have seizures and epilepsy.

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