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Improving methods for paramedics to stop prolonged seizures

Drug delivery directly into muscle using an autoinjector is faster and may be more effective in stopping prolonged seizures, according to a study sponsored by the National Institutes of Health and conducted by a Wayne State University School of Medicine researcher.

The trial compared the effectiveness of two Federal Drug Administration-approved anti-seizure medications and how they are administered to patients suffering prolonged seizures before they arrive at hospitals.

The Rapid Anticonvulsant Medication Prior to Arrival Trial, or RAMPART, was designed to determine whether midazolam or lorazepam are safer and more effective when paramedics are called to treat patients whose seizures aren't stopping. The study was funded by the National Institute of Neurological Disorders and Stroke, part of the NIH.

The prolonged seizures, called status epilepticus, create an emergency situation, said Robert Welch, M.D., professor in WSU's Department of Emergency Medicine, who oversaw the Detroit portion of the study. Estimates indicate that between 120,000 and 200,000 such cases take place each year in the United States. As many as 55,000 people die from the seizures.

Complications of prolonged seizures, Welch explained, include impaired ventilation and aspiration into the lungs, which can result in pneumonia. Other issues include heart rhythm problems and direct injury to the nervous system. "Optimal outcomes in patients therefore depend on treatments that lead to rapid cessation of seizure," Welch said. "In the pre-hospital setting, it can be

difficult to treat this group of patients, particularly since starting an IV to administer medications can be very difficult."

Emergency medical services crews generally administer anticonvulsant drugs at the scene intravenously as a first-line treatment for seizures. However, starting an IV in a patient experiencing seizures can pose a challenge for paramedics and waste precious time. Applying an intramuscular injection using a device similar to the EpiPen – which is used to treat severe allergic reactions – is easier, faster and more reliable, especially in patients having convulsions. The researchers sought to determine whether an intramuscular injection, which quickly delivers anticonvulsant medicine into a patient's thigh muscle, is as safe and effective as giving medicine directly into a vein. The study, which was carried out by paramedics, compared how well delivery by each method stopped patients' seizures by the time the ambulance arrived at the emergency department.

Midazolam and lorazepam are benzodiazepines, a class of sedating anticonvulsant drugs. Midazolam was a candidate for injection because it is rapidly absorbed from muscle. Lorazepam must be given by IV.

The study, published in the *New England Journal of Medicine*, found that 73 percent of patients in the group receiving midazolam via direct injection into the thigh muscle were seizure-free upon arrival at the hospital, compared to 63 percent of patients who received IV treatment with lorazepam. Patients treated with midazolam also were less likely to require hospitalization than those receiving

intravenous lorazepam. Among those admitted, both groups had similarly low rates of recurrent seizures.

"This study demonstrated that giving an intramuscular dose of medication is just as effective in stopping the prolonged seizure as is giving an intravenous medication," said Welch, who also serves as director of clinical research for the department, as well as principal investigator of the Wayne State University hub of the Neurological Emergencies Treatment Trials (NETT) Network. "Since it can be very difficult to establish an IV in a patient who is seizing, giving a medication intramuscularly is easier and may lead to better outcomes. In order to reduce the potential for brain damage, stopping the seizure as soon as possible is the goal of treating status epilepticus. This method is as good, and maybe better, than trying to start an IV and administer medication."

The study involved 1,024 patients nationwide. The WSU portion of the study consisted of 178 enrolled patients, the largest group of patients in the study. Paramedics treated patients in the study who were transported to Detroit Receiving Hospital, Sinai Grace Hospital and St. John Hospital.

Paramedics involved in RAMPART used study boxes with a time-stamped voice recorder. This tool allowed them to make quick decisions, indicate the time treatment began and the time the convulsions stopped, all without having to interrupt patient care to record data. The goal of the study was to control seizures within 10 minutes without having to deliver a second dose of medicine.



Since the study involved patients who were severely affected and could not make decisions for themselves, the research was given exception from informed consent parameters. If patients were unconscious after they were transported to the hospital and the seizure had subsided, a member of the study team attempted to contact a family member. If patients later determined that they no longer wished to continue participating in the study after initial treatment, they could opt out. Community consultation was held in advance of the study to raise awareness, ensure transparency and gain input from residents.

Welch said that when the autoinjectors are available they should become standard equipment in EMS units and ambulances. Until that time, he recommended that paramedics administer midazolam intramuscularly in the thigh using a traditional syringe.

RAMPART investigators said that while autoinjectors might someday be available for use by epilepsy patients and their family members, more research is required. Because of the strong sedative effect of midazolam, on-site medical supervision is now required for patient safety.

The Neurological Emergencies Treatment Trials Network, funded by the NIH, includes more than 100 emergency departments and EMS agencies in 17 major metropolitan areas. The organization was formed to conduct large trials with the goal of reducing the burden of injuries and illnesses affecting the brain, spinal cord and peripheral nervous system. The network, Welch said, explores the narrow window of opportunity that seems to

exist in treating neurologic damage from a variety of conditions, ranging from stroke and traumatic brain injury to seizures and meningitis. The study of rapid interventions by the NETT Network requires the assistance of paramedics treating patients in the field.

About Dr. Robert Welch:

Dr. Welch received a B.S. in microbiology from Michigan State University, an M.D. from Wayne State University, and an M.S. in clinical research design and statistical analysis from the University of Michigan. He is the director of clinical research for WSU's Department of Emergency Medicine. He joined Wayne State in 1987.

For more information about the RAMPART study at WSU, visit: <http://www.detroitrampart.org>

