

New Tool to Treat Stroke More Effectively



A novel device designed to treat stroke more effectively could be made available in the near future. The device is placed onto the head like a sports visor or halo and uses ultrasound to quickly bust clots that cause stroke.

It was developed by William Culp, MD, professor of neurology, surgery and radiology and vice chairman of research at the University of Arkansas for Medical Sciences, and Doug Wilson, assistant director at the Graduate Institute of Technology, University of Arkansas at Little Rock.

Dr. Culp obtained an \$8,000 grant from UAMS that provided him with the materials required for the research project. He and Wilson completed their first patent for "ultrasound for augmented clot lysis" in 2005. The patent, which was licensed in 2006, has been in development by Cerevast Therapeutics.

Dr. Culp's work entailed the use of ultrasound in combination with the clot-busting drug tissue plasminogen activator (t-PA). The aim was to dissolve clots in blood vessels, but the main problem was getting the ultrasound to penetrate the skull. The doctor said ultrasound can be delivered anywhere in a patient's body unless the waves hit something very hard like bone or something very soft like air.

He partnered with Wilson to find a solution that would let the ultrasound waves reach the clot in stroke patients.

The device has 16 transducers scattered around the inside of the device. These transducers, Wilson explained, are designed to line up with the thin points in the skull, such as the temples and the foramen magnum in the base of the skull. Hence, the ultrasound waves can move through the brain with no interruption.

The halo-like device is used after the patient has been administered an IV containing t-PA. The goal is to deliver ultrasound waves wherever the clot is and where the t-PA is working. As a result, the clot disappears faster.

"It makes t-PA work better - improving the clot-busting drug by 40 or 50 percent," Prof. Culp said. "It's like taking a cooking pot and stirring it. The ultrasound stirs the drug around, making it work better."

Phase Three Human Trial

The ClotBust ER®, already in a Phase Three human trial, has been tested in more than 300 patients. So far, none of the results have come back with significant adverse effects, said Dr. Culp, adding that their goal is to test 840 patients.

As the results are looking promising, Dr. Culp noted, there's a possibility that testing could be stopped early by the safety committee. He is optimistic the device will be approved by the start of 2016.

Dr. Culp noted that in the past two decades, there has been a remarkable decrease in strokes nationwide and in Arkansas, which has the highest rate of stroke deaths in the US.

"But for those 800,000 people who will have a stroke in the United States every year, we still have to have good therapy," Dr. Culp said. "This device may well be the next step."

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