MedicalXpress

Clot-busting drug reduces death risk in hemorrhagic stroke patients

February 18 2016

Reporting on the results of a phase III international clinical trial, Johns Hopkins Medicine physicians say use of a cardiac clot-busting drug to treat strokes that cause brain bleeding safely decreased the death rate in patients by 10 percent, compared to a control group receiving saline.

During the five and a half years of the study, the researchers say they also found that "flushing" the unwanted blood from the brain with either the drug or saline (salt) solution was associated with better outcomes for many. Almost 50 percent of patients were home and living independently at 180 days.

Researchers are expected to present results and details of the study, known as the Clot Lysis: Evaluating Accelerated Resolution of Intraventricular Hemorrhage III (CLEAR III) trial, at the International Stroke Conference on Feb. 18 in Los Angeles.

"We found that using the clot-busting drug tPA meant that for every 10 patients treated, one life was saved," says Daniel Hanley Jr., M.D., the Jeffrey and Harriet Legum Professor of Acute Care Neurological Medicine and director of the Brain Injury Outcomes Program at the Johns Hopkins University School of Medicine. "Our results suggest that physicians should begin to think about routinely using it for stable hemorrhagic stroke patients."

Currently, there are no other direct treatments considered approved or safe for hemorrhagic stroke, and the standard of care is supportive,

including blood pressure control, ventilator-assisted breathing and drugs to control brain swelling. Overall, an estimated 50 percent of the 120,000 annual hemorrhagic stroke patients admitted annually to U.S. hospitals die, and only 20 percent of patients return home to live independently.

The drug, tPA, or tissue plasminogen activator, is a synthesized version of a natural protein found on cells that line blood vessels, and has been used to treat heart attacks and strokes caused by blood clots since the late 1990s. Much of the earliest research on tPA was performed at Johns Hopkins by Myron Weisfeldt, M.D., former director of the Johns Hopkins Department of Medicine.

Until the CLEAR trials, which began in 2000, most physicians thought that the drug was unsafe for hemorrhagic stroke patients because it can cause bleeding in the brain. Hanley and his team initially thought the drug might benefit patients by dissolving clots and clearing blood from the brain's ventricles, if given safely after bleeding stopped. The ventricles are cavities deep in the brain normally filled with cerebral spinal fluid.

For the trial, the research team recruited 500 patients of white, African-American and Latino descent, ages 18 to 80, with hemorrhagic stroke from 73 research hospitals. The trial targeted small intracerebral (within the brain tissue) hemorrhages accompanied by a large intraventricular (within the ventricle) hemorrhage.

To qualify for the study, a patient's intracerebral blood clot—typically the size of a pingpong ball—and the accompanying blood in the ventricles had to remain stable, neither growing nor changing its shape, as determined by CT scans over time.

Each patient received blood pressure-reducing treatment to stabilize the

clot and underwent insertion of a brain catheter. After randomization, the catheter was used to flush either 1 milligram of tPA or saline in the ventricle every eight hours for up to 12 doses, or until the ventricles cleared of blood. Each patient was evaluated at 30 and 180 days.

The 249 patients who received the saline had an overall 29 percent death rate, compared to 19 percent with the drug. Patients receiving the drug also had 49 percent adverse events, including fewer bacterial infections in the brain, bleeding and pneumonia, compared to 62 percent in the saline control group.

"Hemorrhage in the brain used to be an essentially untreatable condition, but we now have hope with a therapy that may be effective at saving lives," says coauthor Issam Awad, M.D., the John Harper Seeley Professor of Surgery at the University of Chicago Medicine. "For many patients, this approach can significantly reduce disability after a stroke and can mean going home instead of to a nursing home."

However, Hanley says, the hoped-for extra benefit of tPA in decreasing physical and cognitive disability in all tPA-treated patients did not occur. Some 48 percent of patients—137 people—given tPA were able to go home and live independently, compared to 45 percent—123 people—given saline control. "We had estimated a 13 percent better disability score with the drug and only got a 3 percent difference," Hanley says. "This is going to make many physicians cautious, and rightly so, in terms of outcomes.

"The silver lining to this study is we showed that using the extraventricular drain to flush blood from the brain greatly increased the number of patients able to go home and live independently," says Hanley. "Outside our study, catheter drainage is used in only 8 percent of hemorrhagic stroke cases, and we showed this technique can really make a difference."

The team also performed a protocol evaluation to assess consistency and expertise in administration of tPA, and Hanley says it found room for improvement in the drug delivery process that may increase the drug's effectiveness. The team members plan to address this in a future trial.

Provided by Johns Hopkins University School of Medicine

Citation: Clot-busting drug reduces death risk in hemorrhagic stroke patients (2016, February 18) retrieved 11 May 2024 from https://medicalxpress.com/news/2016-02-clot-busting-drug-death-hemorrhagic-patients.html

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.