

Treatment with clot-busting drug yields better results after stroke than supportive therapy alone

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In an update to previous research, Johns Hopkins neurologists say minimally invasive delivery of the drug tPA directly into potentially lethal blood clots in the brain helped more patients function independently a year after suffering an intracerebral hemorrhage (ICH), a deadly and debilitating form of stroke. Rates of functional recovery with the active tPA treatment far surpassed those achieved with standard "supportive" therapy that essentially gives clots a chance to shrink on their own.

In the current Johns Hopkins-led study, ICH patients who randomly received the minimally [invasive surgery](#) to deliver a drug designed to dissolve their golf ball-sized clots went home from the hospital an average of 38 days sooner than those receiving supportive therapy. In addition to the health benefits, the tPA therapy, and resulting shortened hospital stay, led to a savings of an estimated \$44,000 per patient, the researchers say. ICH has long been considered surgically untreatable under most circumstances; roughly 50 percent of people who have such a stroke die from it.

"This is the most promising treatment that has come along in the last 30 or 40 years for people who have suffered hemorrhagic stroke," says study leader Daniel F. Hanley, M.D., a professor of neurology at the Johns Hopkins University School of Medicine. Hanley is scheduled to present the study's findings at the International Stroke Conference in

Honolulu, Hawaii, Feb. 6 through Feb. 8.

Evidence for the value of active use of the clot-busting drug emerged from follow-up visits of 96 patients from 25 medical centers, all between the ages 18 to 80. Hanley says he hopes this will lead to a larger study of 500 patients. Hanley says the larger-scale study should provide enough information to determine definitively whether the intervention can transform the practice of caring for brain hemorrhage. The drug tPA ([tissue plasminogen activator](#)) has long been used to dissolve clots in the lung and those formed by heart attacks involving major blood vessels. Historically, tPA has not been considered appropriate for [hemorrhagic stroke](#) patients.

Participants in the Minimally Invasive Surgery plus tPA for Intracerebral Hemorrhage Evacuation (MISTIE) trial were treated at the 25 sites in the United States, Canada and Europe. Surgeons at each site performed the procedure by drilling a dime-sized hole in each patient's skull close to the clot location. Using a CT scan that Hanley likens to "GPS for the brain," they guided the catheter through the hole and directly into the clot. The catheter was then used to drip small doses of [tPA](#) into the clot for several days, shrinking the clots roughly 20 percent per day. Those patients who underwent supportive therapy saw their clots shrink by about 5 percent per day.

Hanley says the treatment got rid of much of the clot safely, without cutting through easily damaged brain tissue or removing large pieces of the skull.

"This procedure is technically simple, the equipment and the type of trained physicians needed are available across the country, and if our findings hold up in the larger study we hope to perform, then this therapy could be widely adopted," Hanley says. "It could not only bring benefit to patients but also save money."

ICH is marked by bleeding from a blood vessel in the brain that causes a clot to form and is often caused by uncontrolled blood pressure. The clot builds up pressure in the brain and leaches inflammatory chemicals that can cause irreversible brain damage, often leading to death or extreme disability. The standard of care for ICH patients is general supportive care, usually in an ICU, that includes intense blood pressure control, artificial ventilation, drugs to control swelling and watchful waiting for the clot to dissipate on its own. Invasive surgery is reserved for patients who deteriorate. Currently, only 10 percent of patients undergo the risky and more invasive craniotomy surgery, which involves removing a portion of the skull and making incisions through healthy brain tissue to reach and remove the clot.

Although in the United States just 15 percent of stroke patients have ICH, that rate translates to roughly 70,000 to 100,000 individuals a year—more often than not Asians, Hispanics, African-Americans, the elderly and those who lack access to medical care. The more common form of stroke is ischemic stroke, which occurs when an artery supplying blood to the brain is blocked.

Last year, Hanley and his colleagues reported that 180 days after suffering a stroke, patients in the intervention group were 11 percent more likely to be back to nearly full functioning, with only minor limitations. In the new results, after one year, those who underwent the minimally invasive procedure were 14 percent more likely to have recovered so well. And they found that, across all levels of functioning, patients continued to improve and to do better than those undergoing standard therapy, even a year after their strokes. For example, 13 percent fewer subjects were in long-term nursing care if they were in the group receiving minimally invasive surgery early after their [brain hemorrhage](#).

"We found that, after a year, the healing process is continuing to occur in a differentiated manner, favoring those who had their blood clots

removed as opposed to those who didn't," he says. "The recovery time for a golf ball-sized clot is very long, but recovery can be to high levels of independence, including going back to work. There appear to be drawbacks to leaving the clot in the brain over the long term."

The research was supported by the National Institute of Neurological Disorders and Stroke (R01NS046309).

Also at the conference, several members of Hanley's MISTIE research team will present other findings from the trial results. J. Ricardo Carhuapoma, M.D., an associate professor of neurology, neurosurgery and anesthesiology and critical care medicine at Johns Hopkins, and colleagues found a link between the quantity of blood clot removed from a patient and the level of swelling in the brain. The more blood removed, the lower the level of swelling and the greater the chances of a better recovery, they found.

In another finding, Natalie Ullman, of the Johns Hopkins Department of Neurology's Brain Injury Outcomes Services Division, and colleagues determined that neurosurgeons at medical centers across the world learned to accurately use this GPS-guided method of clot removal with minimal to moderate additional training. The findings suggest that this type of surgery, previously considered quite specialized, can be done all over, eventually allowing for wide access to the new procedure.

Provided by Johns Hopkins University School of Medicine

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