Surgical procedure appears to improve outcomes after bleeding stroke

7 February 2013

A minimally invasive procedure to remove blood clots in brain tissue after hemorrhagic stroke appears safe and may also reduce long-term disability, according to late-breaking research presented at the American Stroke Association's International Stroke Conference 2013.

Of the hundreds of thousands of Americans who have intracerebral hemorrhages (ICH) each year, most are severely debilitated, said Daniel Hanley, M.D., lead author and professor of neurology at Johns Hopkins School of Medicine in Baltimore, Md.

ICH is the most common type of bleeding stroke. It occurs when a weakened blood vessel inside the brain ruptures and leaks blood into surrounding brain tissue, causing neurological damage. There is not a specific evidence-based targeted treatment recommended for ICH and there is no long-term randomized data on surgical treatment.

In one-year results of the Phase II study, MISTIE (Minimally Invasive Surgery plus rtPA for Intracerebral Hemorrhage Evacuation), researchers found that patients treated with surgery and a clot- busting drug had less disability, spent less time in the hospital and were less likely to be in a long-term care facility than other ICH patients.

"There is now real hope we have a treatment for the last form of stroke that doesn't have a treatment—brain hemorrhage," said Hanley, who is also director of the Brain Injury Outcomes Division at Johns Hopkins.

The overall study involved 96 patients at 26 hospitals who had a bleeding stroke. The stage two arm of the trial focused on 25 patients who had the surgical procedure and 31 who were given standard post-stroke medical care, which is medical management only. Patients were average age 60 and 75 percent were men.

During the treatment, surgeons cut a hole the size of a dime in the patient's skull. A catheter is passed into the brain tissue, pushing it through the longest part of the clot, which has formed from blood that pooled during the stroke. Next they apply the clot-busting drug recombinant tissue plasminogen activator (rtPA) to the clot via the catheter every eight hours for about three days. As the clot liquefies, it is removed through the catheter.

The study's patients had blood clots with an average volume of 46 milliliters, about the size of a golf ball, Hanley said. The procedure removed 57 percent of the clots on average, while clots naturally dissolved in only about 5 percent in the standard medical care group in the few days after stroke.

"The normal healing processes may be occurring more rapidly when you remove the blood," Hanley said. "We believe we're actually stopping brain injury and preserving brain tissue that would otherwise be lost."

Researchers found less fluid buildup (edema) in the brains of the surgical patients four days after the procedure, compared with the usual care group.

In six-month results presented last year, researchers noted that the surgical group had 11 percent better functional outcomes. The newest findings showed that a year after the stroke, the advantage in the surgery group had increased to 14 percent.

Likewise, yearlong results among patients with mild disability also showed a 14 percent difference between the treatment groups. Again, more patients from the surgical group improved during that time frame. And compared with the usual care group, 14 percent fewer of the surgical patients were in long-term care a year later.

"That 14 percent shift is occurring across the

spectrum—from long-term care to moderate disability to mild disability," Hanley said.

For patients who underwent the surgical procedure, median time spent in any level of hospital or rehabilitation care was 38 days shorter than for the usual care group. That difference could represent a cost savings per patient of more than $44,000, the researchers estimated.

Researchers noted that no hemorrhage was too large or too deep in the brain to be helped by the procedure. Patients who had surgery between 36 and 72 hours after their stroke fared as well as those treated sooner. Women as well as men, blacks as well as whites, and people over and under age 65 appeared to benefit equally, although a larger study is needed to validate the findings. The researchers hope next to conduct a 500-patient Phase III study at more than 75 sites.

Hanley said the training for surgeons is simple and the equipment is readily available. If the MISTIE findings are confirmed, "then we have a practical treatment that can easily be done by all trained neurosurgeons," he said. "It could make a substantial difference in this disease."

Provided by American Heart Association