Study finds devices no better than meds in recovery from clot-caused strokes

March 14 2013

(Medical Xpress)—When someone has a stroke, time equals brain. The longer a stroke is left untreated, the more brain tissue is lost. Since the only proven treatment—a clot-busting drug—works in less than half of patients, stroke physicians had high hopes for a mechanical device that could travel through the blocked blood vessel to retrieve or break up the clot, restoring blood flow to the brain.

But in a recently completed multi-site trial in which UCLA served as the clinical coordinating center, researchers found there was no overall recovery benefit to patients treated with clot-removal (embolectomy) devices, compared with standard post-stroke care, which includes monitoring blood pressure and ensuring the brain is receiving oxygen.

The study also found that using brain scans to identify which patients might be the best candidates for embolectomy did not lead to better outcomes for those patients.

The study was sponsored by the National Institutes of Health, and the results appeared in the March 7 edition of the *New England Journal of Medicine*.

Treating an acute stroke is always a race against the clock, and the first step is to immediately determine, through the use of a CT or MRI brain scan, whether the stroke is a hemorrhagic stroke, caused by a burst blood vessel, or the much more common ischemic stroke, caused by a clot blocking the flow of blood in a blood vessel.

With an ischemic stroke, the clot-dissolving drug called tissue plasminogen activator, or tPA, is approved for use within three hours of the onset of stroke symptoms. But most stroke victims don't arrive at the hospital within that time frame, and even then, tPA may simply not work. Patients who don't respond to tPA then receive standard post-stroke care, or they may be considered for an embolectomy.

The MR RESCUE (Mechanical Retrieval and REcanalization of Stroke Clots Using Embolectomy) trial sought to determine if imaging the brain to see how much stroke damage has already occurred could identify which patients might be the best candidate for this procedure.

The trial, which began in 2004 and involved 22 sites in the U.S., included 118 patients (average age 65.5) who were treated within eight hours of experiencing an ischemic stroke. All the patients underwent a CT or MRI brain-imaging scan before treatment.

Drawing on information from the scans, the investigators divided the patients into two groups. Patients with a favorable treatment pattern had only a small area of infarct (dead tissue) and a large area of threatened but salvageable brain tissue (called penumbral tissue). Patients with an unfavorable pattern already had a large area of infarct or a small area of penumbral tissue.

Patients from both of these groups were randomly assigned either to receive the standard medical treatment or to have their clot removed by the MERCI Retriever (a tiny corkscrew-like device developed at UCLA that "grabs" clots) or the Penumbra System (a device that sucks clots out). Both devices work by inserting a catheter through the patient's groin to the blocked brain artery.

The hope was that by quickly removing the clot, blood would be restored to the penumbral tissue, thereby saving it. But the results showed that the

level of disability 90 days after suffering a stroke was no different between those patients who underwent the clot-removal procedure and those who received standard care. Rates of death and bleeding in the brain were also the same. In addition, there was no difference between the group in which brain scans showed significant amounts of salvageable brain tissue and those with only a small area of penumbral tissue.

"We found no data showing that imaging could help select patients for treatment, nor did we show an overall benefit of performing an intervention to physically remove the clot," said Dr. Reza Jahan, co-principal investigator for the trial, an associate professor of interventional neuroradiology and a member of the UCLA Stroke Center. "So that was disappointing. On the other hand, there are new devices that open up vessels better and faster, and with fewer complications, than the first-generation devices used in our trial."

Last March, the U.S. Food and Drug Administration approved the use of the next-generation mechanical device. Developed for ischemic stroke, in part by Jahan, the SOLITAIRE Flow Restoration Device dramatically outperformed the Merci Receiver. SOLITARE has a self-expanding, stent-like design, and once inserted into a blocked artery using a thin catheter tube, it compresses and traps the clot. The clot is then removed by withdrawing the device, reopening the blocked blood vessel.

Results of the SOLITARE study showed that the device opened blocked vessels without causing symptomatic bleeding in or around the brain in 61 percent of patients. By comparison, the older MERCI Retriever was effective in 24 percent of cases.

Jahan believes, then, that it would be premature to dismiss the value of endovascular therapy.

"The new devices do work better," he said. "Whether that will translate into improvement in outcomes is not known, and the only way to test efficacy is by doing a controlled trial."

Provided by University of California, Los Angeles