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Interventional stroke therapy needs further study in clinical trials, researchers say

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Devices snaked into the brain artery of a patient experiencing a stroke that snatch and remove the offending clot, or pump a dissolving drug into the blockage, should primarily be used within a clinical trial setting, say a team of vascular neurologists at Mayo Clinic in Florida.

In a commentary published in the May 29 issue of *Mayo Clinic Proceedings*, the physicians say the devices, known collectively as endovascular stroke therapy, should predominantly be limited to use within clinical trials. This is necessary, they say, in order to determine which patients might benefit from use of these devices, and what the risks of such interventional procedures are, when compared to the current standard of care for ischemic stroke. Ischemic stroke, the most common form of stroke, results from a blockage that restricts blood flow in the brain.

A growing number of physicians who treat stroke are currently using these tools, so the recommendation to limit their use to clinical trials will be controversial, acknowledges Kevin Barrett, M.D., co-medical director of Mayo Clinic's Primary Stroke Center in Florida.

Dr. Barrett co-authored the commentary with James Meschia, M.D., and Thomas Brott, M.D., who are also vascular neurologists at Mayo Clinic in Florida.

"Continued use of endovascular stroke therapy outside of clinical trials will further delay the potential to identify those patients who are most

likely to benefit with an acceptable risk profile," Dr. Barrett says. "Using them as part of routine clinical practice without studying their effectiveness in a controlled setting will limit advances in the science of stroke treatment."

The commentary is meant to provide perspective and address questions that arose following the March 7 publication of a study in *The New England Journal of Medicine*. That report concluded that endovascular therapy used after standard stroke therapy—recombinant tissue plasminogen activator (rtPA)—offered similar safety outcomes and no significant difference in benefit to use of rtPA alone. The study was based on results of a 656-patient trial, known as the Third Interventional Management of Stroke (IMS III).

Further background

Use of rtPA has been the standard of care since 1996. The drug, given intravenously, binds to clots and dissolves them to restore blood flow. But it must be used within 3–4.5 hours of the onset of symptoms of a stroke. For patients who present too late to be safely treated with rtPA or have a contraindication to the drug, endovascular therapy is often offered as an alternative treatment strategy at centers with expertise in intra-arterial stroke treatment.

IMS III tested use of several endovascular treatment approaches in following administration of intravenous rtPA. One is the Merci catheter, the first mechanical clot-removing device to be approved (in 2004) by the U.S. Food and Drug Administration. At the time of approval, there was no published evidence that the device was superior to use of intravenous rtPA alone, Dr. Barrett says. The corkscrew-type device is threaded to the brain through the femoral artery in the groin, and it grabs and removes the clot blockage. The other frequently used approach was rtPA delivered directly to the blood clot from within the artery.

Criticisms of IMS III include the infrequent use of newer generation endovascular devices. These devices use a catheter to deliver a retrievable stent that snatches the clot and removes it. "The difference between use of stents for acute stroke and use of stents for blocked heart arteries is that cardiovascular stents are permanently deployed within the artery," Dr. Barrett says.

Conclusions

"Our conclusion is that the sum of evidence, at this point, is that rtPA should remain the standard of care in patients who can be treated between three and 4.5 hours after stroke onset and endovascular stroke therapy should be used within the context of a clinical trial whenever possible," Dr. Barrett says.

Not only has endovascular therapy not shown to offer greater clinical benefit than rtPA, the speed by which these devices can be used is a concern, given the results of IMS III, he adds.

Mayo Clinic in Florida offers several endovascular clinical trials to stroke patients, including a protocol called EARLY that randomizes patients to intravenous rtPA or ultra-early primary endovascular therapy. "We think endovascular therapy likely has a role in acute stroke therapy, but we haven't yet identified the group of patients who will most benefit from it," Dr. Barrett says. "The only way we will get those answers is with well-designed prospective studies."

Provided by Mayo Clinic