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Researchers confirm value of flow-diverting device for most challenging aneurysms

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A multi-center study supports the effectiveness of the newest technology available for the treatment of difficult, life-threatening brain aneurysms. The technology, the Pipeline embolization device, is a flow diverter that redirects blood flow away from wide-necked or giant aneurysms that cannot be treated in more conventional ways.

Andrew Ringer, MD, director of the division of cerebrovascular surgery and professor of neurosurgery and radiology at the University of Cincinnati (UC) College of Medicine, led the Cincinnati portion of the study, which was published in the December issue of *Neurosurgery*.

"The study showed that the Pipeline device is a safe and effective tool for patients and surgeons," says Ringer, a Mayfield Clinic neurosurgeon who has treated 11 patients with the device. "This expands our ability to safely treat aneurysms that were very difficult to treat before."

A brain aneurysm is bulge on an artery wall that can rupture as it grows thinner and weaker, releasing blood into the space between the brain and the skull, a potentially catastrophic event called a subarachnoid hemorrhage. Of the 30,000 Americans who experience a ruptured brain aneurysm each year, according to the American Association of Neurological Surgeons, about 40 to 50 percent survive, while 20 percent recover without any permanent physical deficits.

The U.S. Food and Drug Administration approved the flow-diverting device in 2011 after the successful completion of a clinical trial known

as PUFS (Pipeline for Uncoilable or Failed Aneurysms). Ringer and his colleagues from six other neurosurgical centers—all part of the Endovascular Neurosurgery Research Group (ENRG)—opted to continue studying the Pipeline, which is manufactured by ev3/Covidien, to better understand its safety and effectiveness in real-world hospital settings.

"Whenever there is a new device, technology or drug that is undergoing review for FDA approval, the sponsors of the study will select clinical sites that have high-level expertise, that treat many cases of this type very well, and that have the infrastructure necessary to run the study," Ringer said. "The results that come out of these studies, therefore, are the results at the most experienced centers. More importantly, the results are done under the very rigid confines of a clinical trial and are not necessarily reflective of everyday practice."

Investigators from ENRG wanted to know whether outcomes would remain consistently positive after the device was approved and was being used in clinical practice. "We asked this question because there have been instances where an approved device did not perform as well in a real-world setting as it had in a clinical trial leading up to its approval," Ringer says.

In the case of the flow-diverting Pipeline, Ringer continues, the device lived up to expectations. "We tracked the outcomes of patients who had the Pipeline used for aneurysm treatment in standard practice, outside the confines of a study, and we were able to show that the outcomes in fact were quite good."

The study tracked the outcomes of 56 patients treated at the seven centers. Clinicians used an average of two Pipeline devices to treat each aneurysm, and they used coils as well in treating 25 percent of the aneurysms. Of the 19 patients who had a three-month follow-up

angiogram, 68 percent had complete, successful occlusion of their aneurysm. The study also reported, in its "most surprising finding," a major complication rate, resulting in permanent disability or death, of 8.5 percent. Four patients with giant aneurysms suffered fatal hemorrhages following their procedure.

"While any adverse outcome is cause for regret, we recognize that these patients had high-risk aneurysms, and other treatment options or observation may have been even riskier," Ringer says. "We will continue watching outcomes as the device becomes more available."

Ringer and his colleagues are using the flow-diversion device to treat three types of brain aneurysms:

- Saccular or berry, which have a neck at their origin on the main artery and a dome that can expand like a balloon.
- Wide-necked or fusiform, which do not have a defined neck.
- Giant, which are more than 2.5 centimeters in diameter.

Standard treatments for brain aneurysms include a surgical procedure called clipping, in which the surgeon opens the skull and places a clip over the aneurysm's neck, and a less invasive, endovascular procedure called coiling, in which the surgeon uses a catheter to deliver and deposit tiny coils into the aneurysm. Another endovascular procedure involves filling the aneurysm with a special glue that hardens.

Wide-necked and giant aneurysms have proven resistant to these treatments, however, because they have no necks that can be clipped and because coils or glue tend not to remain within the aneurysms' open mouths.

The flow-diverting device addresses this problem through the placement

of a stent-like scaffold over the healthy artery outside the aneurysm. The scaffold is a tiny braided mesh cylinder, 10 to 35 millimeters long, which is made of platinum and nickel-cobalt alloy.

"When using this treatment we never go inside the aneurysm," Ringer said. "The tightly woven tube creates resistance to the blood flow, causing the blood to continue down the artery along the path of least resistance, causing the aneurysm to eventually clot off, wither and die."

Unlike clipping and coiling procedures, which neutralize blood flow to an aneurysm almost immediately, a flow-diversion device may require weeks or months to neutralize an aneurysm. "But the advantage of the Pipeline is that we don't have to work inside the aneurysm," Ringer said. "And therefore, if the shape, size, or configuration of the aneurysm is such that both surgery and coiling are difficult or dangerous, we have another option."

Provided by University of Cincinnati Academic Health Center

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