New 'pipeline' device offers new option for difficult-to-treat aneurysms

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A new technology called the Pipeline embolization device (PED) shows encouraging results in patients with certain types of difficult-to-treat brain aneurysms, reports the December issue of *Neurosurgery*, official journal of the Congress of Neurological Surgeons.

Data collected since the PED was approved for marketing show generally good results in "real world" clinical practice. However, the report raises concerns about fatal bleeding and other serious complications, especially for aneurysms in one specific location. The lead author of the study was Dr. Peter Kan of University at Buffalo, N.Y.

Pipeline Device Shows Promising Results…

The researchers evaluated "early postmarket" results—that is, after approval by the U.S. Food and Drug Administration (FDA)—using the PED at seven surgical centers. The PED is designed for use in treating certain types of aneurysms that can't be blocked off by surgery or other treatments, such as "wide-necked" or giant aneurysms.

An aneurysm is a weakened spot in a blood vessel wall. If the aneurysm enlarges or ruptures (breaks), it can cause a stroke or life-threatening bleeding in the brain. The study reflects the increased emphasis on collecting postmarketing data on newly approved medical devices to see if the results in initial clinical experience are comparable to those in

research trials. The PED received FDA approval for use in treating specific types of brain aneurysms in 2011.

The study included 62 PED procedures performed to treat aneurysms in 56 patients. The patients' average age was 59 years. More than 40 percent of the aneurysms were discovered incidentally, before they caused any symptoms or bleeding.

On average, it took two PEDs to treat each aneurysm. Some patients needed additional procedures related to problems deploying the PEDs. In one-fourth of aneurysms, additional "coil" treatments were used in addition to PEDs to help block off the aneurysm.

Three-month follow-up data were available for 19 patients. In 68 percent, the aneurysm was completely blocked off. Two patients had some narrowing within the Pipeline device—this was successfully treated with an additional angioplasty procedure.

…But Also Some Serious Complications

However, the data also showed substantial risks, including an 8.5 percent rate of major complications or death. Six patients had clots leading to strokes or transient ischemic attacks ("mini strokes") after the PED procedure. Most of these patients had vertebrobasilar aneurysms—located in an area at the base of the brain where three major arteries meet.

In addition, four patients suffered bleeding, which developed up to two months after the PED procedure. Bleeding was fatal in all four cases.

Unlike surgery or other treatments for brain aneurysms, the PED does not achieve immediate occlusion. Rather, the "Pipeline" redirects blood flow away from the aneurysm and through the parent vessel. Over time,

new blood vessel tissue grows across the neck of the aneurysm, blocking it off permanently.

This initial "real world" experience with the PED shows results similar to those achieved in clinical trials leading to FDA approval. Although treatment may take months to complete, the aneurysm is eventually completely occluded in most patients. Thus the PED offers an effective new option for patients with aneurysms that would previously have been difficult or impossible to treat.

The postmarketing data also show a significant risk of serious complications, including potentially fatal bleeding. Pending further study, Dr. Kan and colleagues caution against "off-label" use of the PED to treat aneurysms in the vertebrobasilar region. They conclude, "Long-term data are needed to establish long-term efficacy and to understand the delayed complications of this new technology."

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