FDA approval of brain aneurysm device gives Jefferson neurosurgeons another life-saving tool

April 18 2011

The recent U.S. Food and Drug Administration (FDA) approval of a brain aneurysm device has opened the door for neurosurgeons at Jefferson Hospital for Neuroscience (JHN) to offer advanced treatment to patients suffering from large or giant aneurysms who otherwise have limited, effective options.

"With this FDA approval, the team of neurosurgeons here at JHN has a better tool to block and shrink these types of aneurysms, saving lives and vision in some cases," said Fernando Gonzalez, M.D., assistant professor in the Department of Neurological Surgery, Division of Neurovascular Surgery and Endovascular Neurosurgery at JHN, who performed the procedure using the stent, known as a Pipeline Embolization Device (PED).

PED is a flexible mesh tube made of platinum and nickel-cobalt chromium alloy that blocks off large, giant, or wide-necked aneurysms in the internal carotid artery, a major blood vessel supplying blood to the front of the brain. It also reduces the chance of rupture and eliminates the need for invasive surgery.

Prior to the FDA approval, Dr. Gonzalez used PED under "compassionate-use" exemption to treat four life-threatening aneurysms in a procedure done at JHN, the region's only facility exclusively dedicated to neurology and neurosurgery. Jefferson is the first hospital in

Pennsylvania, New Jersey and Delaware to use the device on a patient.

The FDA decision now allows Jefferson's renowned team of vascular neurosurgeons, who are among the busiest in the nation performing both open and endovascular procedures, to offer better treatment to other patients in this subset (about 10 percent of the 30,000 brain aneurysms cases in the United States per year) who wouldn't benefit from coils or traditional stents because of the size of their aneurysm.

"Numerous studies have shown that in certain types of surgery experience, the number of cases a surgeon and an institution perform has an impact on quality and patient outcomes," said Robert H. Rosenwasser, M.D., chairman of the Department of Neurological Surgery at Thomas Jefferson University. "Volume does matter, and it clearly matters for patient outcomes in neurosurgical cases for brain tumors, vascular and endovascular procedures, spinal surgery and for both surgical and medical treatment of stroke."

"JHN easily ranks in the top five for each of these treatments," he adds.

Dr. Gonzalez, who is one of the few people with experience with the device on the East Coast, used the PED on a Jefferson patient who had four aneurysms on her carotid and ophthalmic arteries. Open surgery wasn't an option because the patient was on blood thinners for Sickle Cell Anemia, so Dr. Gonzalez filed for paperwork with the FDA for "compassionate-use" of the device. The procedure was approved and performed with great success—the aneurysms have since completely disappeared.

"Because of our experience in endovascular treatments and with the device we are going to be proctors nationally as the PED is rolled out," Dr. Rosenwasser said.