Northwestern study compares endovascular brain aneurysm repair devices

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Approximately 6 million Americans have brain aneurysms, a condition that occurs when a weak or thin spot develops on a blood vessel in the brain causing it to balloon. Often, these do not cause symptoms and go undetected, but every year an estimated 30,000 Americans experience a ruptured aneurysm that bleeds into the brain causing a life threatening injury. Immediate medical treatment is necessary to prevent stroke, nerve damage or death, and includes surgery or coiling. Coiling is an approach that blocks blood flow to the aneurysm by filling it with platinum coils. While less invasive than surgery, the likelihood of future aneurysm recurrence and subsequent treatment is higher with coiling. In an effort to lower the risk for repeat aneurysm treatment after coiling, Northwestern Medicine researchers are examining a new type of gel-coated coil to determine if it is more effective than the standard bare coils in preventing aneurysm recurrence.

Aneurysms can be a very serious health threat, according to Bernard R. Bendok, MD, a neurosurgeon at Northwestern Memorial Hospital, who is the principal investigator for the new generation Hydrogel Endovascular Aneurysm Treatment Trial (HEAT). "When an aneurysm needs treatment, it is important to perform the safest, most effective and most durable treatment. This clinical research trial, called HEAT, will help us determine whether bare platinum coils, which have been used for years, or the newer gel-coated coils are more effective long-term," said Bendok, who is also an associate professor of neurological surgery and radiology at Northwestern University Feinberg School of Medicine.

Coiling involves inserting a catheter into an artery and threading it through the body using live x-rays as a guide to the site of the aneurysm. Coils are passed through the catheter and released into the aneurysm filling it to block blood from entering. Blood clots then form around the coil preventing the vessels from rupturing or leaking and destroying the aneurysm.

"Coils are not always able to fill the aneurysm completely, which leaves dead space in the aneurysm. This space has been associated with a higher rate of aneurysm recurrence," explained Bendok. "The new coils are made with platinum and a hydrogel that expands over time to eliminate the space between the coils, potentially limiting the need for future treatment."

HEAT is an international randomized study that seeks to determine how the gel packed coils measure up to the standard option in preventing future aneurysm recurrence. Northwestern is the lead site for the trial. Patients may be eligible for the trial if they are between the ages of 18 and 75 years with aneurysms 3 to 14mm in size, amenable to coiling. An estimated 30 sites around the world are expected to join the trial which has an enrollment goal of 600 participants.

On average aneurysms impact about one percent of the adult population. Understanding symptoms and risk factors can be potentially lifesaving. Small aneurysms may not be associated with symptoms, but a larger, growing aneurysm may cause pressure on tissues and nerves, leading to symptoms including headache, pain above and behind the eye, a dilated pupil, double vision, and weakness, numbness or paralysis on one side of face or body.

"In many cases, brain aneurysms remain silent until there's a major problem," said Bendok. "Most are not found until they rupture or are found incidentally on brain images taken to assess another condition.

The number one sign to look for is a sudden and extremely severe headache. If this occurs, one should seek immediate medical attention."

Other indicators that a person may have a ruptured aneurysm include double vision, nausea, vomiting, stroke-like symptoms, stiff neck, loss of consciousness and in some cases, seizure and changes in memory. Risk factors include hypertension, alcohol and drug abuse, and smoking. Aneurysms can be influenced by genetic factors and family history may be an indication for screening. People with certain hereditary diseases including connective tissue disorders or polycystic kidney disease can have a higher occurrence. Other associations include arteriovenous malformation (AVM) and blockage of certain blood vessels in the brain. Women are more likely than men to have brain aneurysms. It's estimated about 10 in every 100,000 people will experience a ruptured aneurysm each year.

"Brain aneurysm rupture can be very devastating," said H. Hunt Batjer, MD, chairman of the department of neurological surgery at Northwestern Memorial and Michael J. Marchese Professor of neurological surgery at the Feinberg School. "It's important to know what to look for and who might be at increased risk for aneurysm disease. While current treatments are effective, trials like HEAT have the potential to advance the art and science of brain aneurysm treatment and lead to even better treatment options in the future."

More information: To learn more about the HEAT trial, visit clinicaltrials.gov/ct2/show/NCT01407952

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