Device advances interventional radiology treatment to clear blocked carotid arteries, prevent stroke

March 15 2010

An important interventional radiology advancement—the use of a new cerebral protection device in combination with FDA-approved carotid stents in high-surgical-risk patients—provides a minimally invasive, safe and effective way to prevent stroke from occurring during treatment to clear blocked carotid arteries, according to research released at the Society of Interventional Radiology's 35th Annual Scientific Meeting in Tampa, Fla.

"Interventional radiologists are at the forefront in advancing stroke care. Using a new FDA-approved cerebral protection device during carotid artery stenting effectively reduces and captures particles released during the stenting procedure in order to prevent this debris from travelling to the brain where it has the potential to cause a stroke," noted Barry T. Katzen, M.D., FSIR, interventional radiologist and medical director of Baptist Cardiac and Vascular Institute in Miami, Fla. "The Mo.Ma® device, which uses balloons that are inflated and act like endovascular surgical clamps to protect the brain during the procedure, provides a treatment option for patients who may not be healthy enough to undergo surgery, for example, those with severe heart or lung disease or those who have had neck operations or radiation for neck tumors. The Mo.Ma device provides an important alternative to surgery for stroke prevention," he added. In the study, 262 patients were enrolled at 25 investigational sites in the United States (20) and the European Union (5) between September 2007 and February 2009. At 30 days, the major

adverse cardiac and cerebrovascular event rate (MACCE) of stroke, death and heart attack was 2.7 percent, with the major stroke rate through 30 days at less than 1 percent—compared to a 13 percent MACCE rate typically derived from previous carotid stenting trials. A low MACCE rate demonstrates the safety and effectiveness of the device in clinical use, said Katzen. "Interventional radiologists are critical members of stroke teams in hospitals—working with emergency room physicians and neurologists in combating stroke, the third leading cause of death in the United States," said Katzen. "This device and interventional radiology treatment are added tools to improve stroke prevention," said Katzen. While there are "debris catcher" and other balloon occlusion devices currently available, the Mo.Ma device refines carotid stenting treatment.

Every 45 seconds someone in the United States has a stroke; every three minutes someone dies from a stroke. Each year, 600,000 Americans will have a new or recurrent stroke and, of these, 160,000 will die. A stroke occurs when a blood vessel carrying oxygen and nutrients to the brain is blocked by a clot or bursts, causing the brain to starve. If deprived of oxygen for even a short period of time, the brain nerve cells will start to die. Once the brain cells die from a lack of oxygen, the part of the body that section of the brain controls is affected through paralysis, language, motor skills or vision, said Katzen. Strokes caused by blood clots that block the artery are ischemic strokes, the most common type, accounting for 70□□ percent of all strokes.

As vascular experts, interventional radiologists treat atherosclerosis, "hardening of the arteries," throughout the body. In some patients, plaque buildup in the carotid artery may result in stroke by either decreasing blood flow to the brain or by breaking loose and floating into a smaller vessel, depriving a portion of the brain of blood flow. In patients at high risk of having a stroke, the narrowed section of artery may be reopened by an interventional radiologist through angioplasty

and reinforced with a stent, thereby preventing the stroke from occurring. Vascular stents are typically made of woven, laser-cut or welded metal that permits the device to be compressed onto a catheter and delivered directly into the hardened artery.

"Interventional radiologists are leaders in participating in clinical trials using minimally invasive new technologies. The data collected in the ARMOUR trial have led to FDA clearance, thus allowing broader physician access to the Mo.Ma proximal cerebral protection device in the treatment of patients with carotid artery disease," noted Katzen. In the ARMOUR trial, patients with carotid artery disease and who were not suitable candidates for carotid artery surgery were considered for carotid artery stenting accompanied by the use of the MO.MA device. Patients who provided written informed consent and met inclusion/exclusion criteria were enrolled in the ARMOUR trial, a pivotal, prospective, multicenter, nonrandomized trial to evaluate the safety and effectiveness of the device. The average age of the patients was 75 years, and nearly 29 percent were octogenarians. Nearly 67 percent were men. Patients were assessed at 30 days to measure the continued success of the procedure and any ill effects that may have occurred. Following Food and Drug Administration review, Invatec Inc. received clearance to market the Mo.Ma device for use during carotid artery stenting in the United States.

The Mo.Ma device establishes full-time cerebral protection during the carotid stenting procedure prior to crossing the internal carotid artery lesion. It is comprised of two small balloons that are inflated in the external carotid artery and the common carotid artery to suspend blood flow during the stenting procedure. The balloons act like endovascular surgical clamps, protecting the brain during the procedure. The suspended blood is then aspirated along with any particles to complete the procedure safely.

Provided by Society of Interventional Radiology