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Data from the ARCHeR Trial Shows Carotid Stenting for Stroke Prevention is Safe and Effective For High-Risk Patients Interventional Radiology Procedure More Effective Than Surgery in Keeping Blood Vessels Open; Less Need for Retreatment

Phoenix, Arizona (March 25, 2004) – Research presented in a six-hour symposium on carotid artery disease at the 29th Annual Scientific Meeting of the Society of Interventional Radiology showed carotid artery stenting to be safe and effective for high-risk patients. Currently, the standard of care for stroke prevention in patients with moderate to severely blocked carotid arteries is carotid endarterectomy surgery. The ARCHeR trials treated patients who were high-risk surgical candidates with carotid artery stenting with and without embolic protection, a device to capture debris that may break off during the procedure.

This multi-center study at 48 sites in the U.S., Europe and Argentina included 581 consecutive patients in a series of three, single arm trials. The ARCHeR 1 trial used just the stent, the ARCHER 2 trial included the stent plus embolic protection, and the ARCHER 3 used a newer version of the catheters for delivering the stent and embolic filter, known as the rapid exchange system. The 30-day adverse event rate counting all strokes, deaths or heart attacks were 7.6, 8.6, and 8.3 percent for ARCHER 1, 2, and 3 respectively. The incidence of major stroke or death in the first 30 days was low in all trials; 3.8, 2.5 and 2.8 percent, for ARCHER 1, 2, and 3 respectively.

One-year data is available for ARCHeR 1 and 2 and this composite endpoint includes the 30-day event rate for stroke, death and heart attack plus stroke on the same side as the carotid stent (ipsilateral stroke) up to 12 months. At one year, the major adverse event rate (MAE) was 8.3 percent and 10.2 percent for ARCHER 1 and 2, respectively. The one-year data is still being collected for ARCHER 3. The studies, sponsored by Guidant Corporation, used the ACCULINK stent and the ACCUNET embolic protection filter.

The comparative rates for the surgery, using the same composite endpoint for one year, is 14.5 percent, based on the rates in the published medical literature for both carotid endarterectomy surgery and for medical therapy in high-surgical risk patients. This literature control was used so that patients at high risk for surgery were not subjected to surgery.

"This study shows that carotid stenting is safe, even in the high-risk group," says interventional radiologist Mark Wholey, M.D., an ARCHeR trial principal investigator presenting this data at the Society of Interventional Radiology's Annual Scientific Meeting.

Because the carotid surgery is an established safe treatment, the study only included those patients who were high risk because they were too sick for surgery or anatomically would not have been good surgical candidates. "We are excited that we are getting proof of carotid stenting in the high-risk group, and we look forward to the results of studies like CREST that are studying stenting in lower risk populations; although we certainly expect it to be safer than surgery in low-risk populations, too," says Wholey.

The rate at which the artery became reblocked and required a repeat procedure at one year was low, at 2.2 percent for ARCHeR 1 and 2.8 percent for ARCHER 2. "This is quite good because the known published rate for the artery to reblock after the surgery is 4 to 7 percent. So carotid stenting is a durable procedure that is more effective than the surgery in keeping the vessel open, with less need for retreatment. The whole purpose of keeping the carotid vessel open is to prevent future strokes from happening and the long-term data on the effectiveness of the ACCULINK stent for doing this is very impressive," commented Wholey. In the follow-up period from 31 days to one year for the 436 patients from ARCHER 1 and 2 there was not one single fatal stroke and only one major stroke.

Carotid Artery Disease and Stroke

"Patients with severely blocked carotid arteries are at high risk for stroke. Obesity is a major contributor to vascular disease, including carotid artery disease. America needs to take obesity seriously -- carotid artery disease and subsequent strokes are preventable events for many people," says Wholey. Across the studies, approximately 40 percent of the patients had diabetes, and two-thirds had a history of angina or heart attack. These are all obesity-related conditions.

As vascular experts, interventional radiologists treat artherosclerosis, "hardening of the arteries," throughout the body. In some patients, atherosclerosis, specifically in the carotid artery in the neck that delivers blood to the brain, can lead to ischemic stroke. Plaque in the carotid artery may result in a stroke by either decreasing blood flow to the brain or by a piece breaking loose, known as an embolus, which can float to a smaller artery and block the blood flow to the brain, causing a stroke. In patients at high risk of stroke, the narrowed section of the carotid artery may be re-opened through angioplasty and reinforced with a stent, thereby preventing the stroke from occurring. This trial included a small filter with the stent, known as embolic protection, to catch debris that might break loose during the procedure, thus minimizing procedure-related stroke.

About the Society of Interventional Radiology

An estimated 5,000 people are attending the Society of Interventional Radiology's 29th Annual Scientific Meeting in Phoenix, Arizona. Interventional radiology is the medical specialty devoted to advancing patient care through the innovative integration of clinical and imaging-based diagnosis and minimally invasive therapy. Interventional radiologists are physicians who specialize in minimally invasive, targeted treatments performed using imaging for guidance to treat disease non-surgically through the blood vessels or through the skin. Interventional radiologists pioneered modern medicine with the invention of angioplasty and the catheter-delivered stent, which were first used to treat peripheral arterial disease. Interventional radiology procedures are a major advance in medicine that do not require large incisions – only a nick in the skin – and offer less risk, less pain and shorter recovery times compared to open surgery. More information can be found at <u>www.SIRweb.org</u>.

Interviews, medical illustrations and X-ray image are available by contacting the press office on site at 602-514-7890.

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