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**Second Major Study of Carotid Stenting Reproduces Results of  
Previous Large Study and Proves Treatment is Safe and Effective for  
High-Risk Patients to Prevent Stroke**

***CASES-PMS Trial of Carotid Stenting with Embolic Protection in High Surgical Risk  
Patients Shows Similar Results Regardless of Hospital, Physician Volume, or  
Physician Experience Via a Formal Training Program***

SEATTLE, Washington (March 2, 2007) – A multi-center, prospective, single-arm trial of 1,493 patients adds to the growing body of evidence that carotid stenting with embolic protection is safe and effective for patients at the highest risk for adverse events, and substantiates the low adverse event rates reported previously in the SAPHIRE trial. The preliminary one-year data from 73 sites, presented today at the Society of Interventional Radiology's 32<sup>nd</sup> Annual Scientific Meeting, compares the outcomes of patients in the CASES-PMS trial to those of the SAPHIRE trial stent cohort, and confirms the long-term results and safety profile of carotid stenting with embolic protection in patients who are high-risk for surgery or whose surgery failed – the population for whom the treatment is currently approved. The overall stroke rate in the CASES-PMS trial was 4.8 percent at one year. This trial studied the treatment using 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. Physicians of varying experience levels at multiple institutions performed the carotid artery stenting utilizing a formal training program and had similar adverse event rates to the highly experienced experts in the SAPHIRE trial, showing that the training program is valuable and can contribute to patient safety in introducing a relatively new interventional procedure into the mainstream.

The primary endpoints of the study measured the 30-day major adverse event rate (MAE) – death, stroke and heart attack – which were likely to be procedure-related events, and the one-year MAE, which included the 30-day rate plus death and same-side stroke from 31 days to one year. The preliminary one-year cumulative MAE of 11.9 percent in the CASES-PMS trial is similar to the 12.2 percent rates seen with the SAPHIRE trial stent cohort, and lower than the 20.1 percent for the surgical arm of the SAPHIRE trial. The CASES-PMS overall stroke rate at one-year was 4.8 percent (seven percent in symptomatic patients and 4.2 percent in asymptomatic).

“Patients with severely blocked carotid arteries are at high risk for stroke, but many patients with vascular disease are not good candidates for surgery. Now we know we can safely offer these high-risk patients carotid stenting, saving many people from future

strokes,” says Barry T. Katzen, M.D., interventional radiologist, Baptist Cardiac and Vascular Institute, Miami, FL.

The CASES-PMS trial was designed to assess the safety and efficacy outcomes of carotid artery stenting using the Cordis PRECISE® Nitinol Stent and ANGIOGUARD™ Emboli Capture Guidewire, when performed by physicians with varied experience in carotid artery stenting utilizing a formal training program. The study demonstrated that using a detailed training program in carotid artery stenting for physicians with various levels of experience produced outcomes that were similar to those of the highly experienced physicians who participated in the SAPHIRE trial.

“We are excited to see a similar safety profile for physicians who were involved in the training program at 73 different sites. This is an excellent model to introduce a new technique very safely into the mainstream, and will allow us to train more physicians, enabling more patients to have this important treatment to prevent stroke,” says Katzen.

### **Carotid Artery Disease and Stroke**

As vascular experts, interventional radiologists treat atherosclerosis, “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. 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. The device 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.

### **Benefits of Stenting, an Interventional Procedure**

In addition to the lesser risk of major adverse events, there are many other benefits to the balloon angioplasty and stenting treatment, an interventional radiology procedure. Because there is no incision, cranial nerves are left untouched during the procedure. This is an important benefit because cranial nerve damage, which can cause difficulty talking and swallowing, occurred in 4.8 percent of the overall SAPHIRE trial surgical patients and has been reported as high as nine percent in other surgical studies. (There was no surgical arm in the CASES-PMS trial). In addition, the patient can go home the next day, there is no general anesthesia and no infection rate for the interventional procedure.

### **About the Society of Interventional Radiology**

Interventional radiologists are board-certified physicians who specialize in minimally invasive, targeted treatments. They offer the most in-depth knowledge of the least invasive treatments available coupled with diagnostic and clinical experience across all specialties. They use X-rays, MRI and other imaging to advance a catheter in the body, usually in an artery, to treat at the source of the disease nonsurgically. As the inventors of peripheral angioplasty and the catheter-delivered stent, interventional radiologists pioneered minimally invasive modern medicine, and provide treatments that offer less

risk, less pain and less recovery time compared to open surgery. More information can be found at [www.SIRweb.org](http://www.SIRweb.org).

***Local interviews, medical illustrations and broadcast quality video footage are available by contacting SIR's Communications Department at [Emily@SIRweb.org](mailto:Emily@SIRweb.org) or (703) 691-1805.***

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