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Carotid Stenting to Prevent Stroke is Much Safer in High-Risk Diabetic Patients than Surgery: New Study

SAPPHIRE Trial shows patients at highest risk for adverse events had significantly better results with the minimally invasive interventional radiology procedure compared with surgery

Phoenix, Arizona (March 25, 2004) – High-risk diabetic patients who underwent carotid stenting had far fewer heart attacks and significantly less major adverse events overall at one-year follow-up than those who underwent carotid endarterectomy surgery to prevent stroke, according to data presented today at the 29th Annual Scientific Meeting of the Society of Interventional Radiology. The stenting group had a 2.4 percent incidence of heart attacks compared with an 18.2 percent incidence in the surgical group. Incidence of major bleeding was 4.8 percent for the stenting group versus 20.5 percent for the surgery group. The one-year major adverse event rate -- which includes death, stroke and heart attack to 30 days plus same-side stroke and deaths due to stroke from 31 to 360 days -- was 4.8 percent for stenting versus 25 percent for surgery.

The study also collected the 30-day event rate for any type of stroke, heart attack or death. The 30-day event rate for stroke, heart attack and death was 4.8 percent for stenting and 22.7 percent for carotid surgery and was statistically significant. These results are data of the high-risk diabetic arm of the SAPPHIRE trial, a prospective, multi-center, randomized, controlled trial at 29 U.S. centers comparing the safety and efficacy of carotid stenting with embolic protection to standard carotid surgery to treat blocked carotid arteries to prevent stroke. The products used in the study, sponsored by Cordis Endovascular, a Division of Cordis Corporation, a Johnson & Johnson company, were the PRECISE™ Stent with the ANGIOGUARD™ Filter.

"These findings are quite significant because diabetics are at greater risk for all vascular events. This study shows that stenting is far safer than surgery even in this highest risk population. It clearly establishes that all high-risk diabetics should have stenting, not surgery," says interventional radiologist Mark Wholey, M.D. a SAPPHIRE trial principal investigator presenting this data at the Society of Interventional Radiology's Annual Scientific Meeting.

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, there is no damage to the cranial nerves that can occur with surgery. This nerve damage, which can cause difficulty talking and swallowing, occurred in 4.8 percent of the overall SAPPHIRE trial surgical patients and has been reported as high as 9 percent in other surgical studies. In addition, the patient can go home the next day, there in no general anesthesia, no infection rate, and the interventional procedure only takes about 20 – 30 minutes.

Carotid Artery Disease and Stroke

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.

Diabetic patients are at greater risk in general for all vascular conditions throughout the body such as peripheral arterial disease, carotid artery disease and stroke, coronary artery disease and heart attack, and abdominal aortic aneurysm. Because they are prone to vascular disease and calcification, or hardening of the plaque in the carotid artery, their artery is less elastic, making them more prone to artery dissection and reclogging of the artery after treatment. They have a high complication rate for surgery, but are also more difficult to treat with angioplasty and stenting.

"Patients with severely blocked carotid arteries are at high risk for stroke. These findings offer hope for those patients who need treatment of their carotid artery disease to prevent stroke, but were too high risk to have the surgery. Now we know we can safely offer them carotid stenting," says Wholey.

About the Study

The study involved a total of 334 high-risk patients who were randomized and treated by either stenting with embolic protection or surgery in the overall multi-center SAPPHIRE trial; the high-risk diabetic subset reported on today was composed of 86 patients. This diabetic population was at high risk for adverse events, and some at extreme risk; for example they couldn't walk across the room, had unstable angina, or already had bypass surgery, or other heart disease.

"All of the SAPPHIRE trial patients were high risk and the earlier data on the total study population showed the stenting to be safer than surgery. This diabetic subset were at even higher risk, and these new data not only substantiate and confirm the earlier

findings, but show even more dramatically that stenting is safer than surgery in those at high risk," says Wholey.

The primary endpoints of the study measured the 30-day major adverse event rate (MAE), 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.

Thirty-Day Data
The 30-day MAE included death, any stroke, or heart attack that occurred. In the high-risk diabetic population, the 30-day event rate for death, stroke or heart attack was 4.8 percent for stenting and 22.7 percent for carotid surgery, which was statistically significant.

One-Year Data
The one-year MAE rate included the 30-day MAE rate plus deaths and same-side stroke between 31 days and one-year. This included all deaths that occurred, even those that were unrelated. The overall one-year major adverse event rate was 16.7 percent for stents versus 31.8 percent for surgery, showing a trend favoring carotid stenting.

However, the combination of the 30-day MAE rate with same-side strokes and deaths due to stroke (neurologic death) from 31 days to one-year resulted in a major adverse event rate that was 4.8 percent for stenting versus 25 percent for surgery at one year and was statistically significant.

Statistically significant differences at one-year follow-up were also observed for stenting over surgery for heart attack, 2.4 percent versus 18.2 percent; and major bleeding, 4.8 percent versus 20.5 percent. The incidence of stroke in diabetic patients was lower in the stent group at 2.4 percent compared to 11.4 percent in the surgery group, but the difference was not statistically significant.

"We thought the initial SAPPHIRE results in the overall high-risk patients were exciting. However, these new data from the high-risk diabetic subset shows even more dramatically that stenting is safer than surgery in all high-risk patients, because the diabetic group is very high risk," says Wholey. The one-year heart attack rate for the SAPPHIRE high-risk group overall was 2.5 percent for stenting versus 7.9 percent for surgery, but for the high-risk diabetic subgroup, it was 2.4 versus 18.2 percent.

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 www.SIRweb.org.

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

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