It's neck-and-neck down the long stretch for 2 stroke-prevention procedures

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Like horses running down the long stretch of a race track, two different artery-opening treatments appear to be running neck-and-neck when it comes to preventing stroke among people with clogged neck arteries and other health problems.

After three years, patients who had a minimally-invasive procedure were just as likely to suffer a stroke or heart attack, or to die, as those who had open-neck surgery.

The findings should help guide the treatment of patients who need to have one of the two carotid arteries in their necks un-clogged to reduce their risk of a stroke — but who face a high risk of complications during surgery because of other health issues. Such patients may do better with the minimally invasive option, called carotid stenting.

But the study, called SAPPHIRE, doesn't settle the question for many other patients, for whom the open surgery — carotid endarterectomy — is a tried-and-true option.

The results, from 260 patients who were randomly assigned to one of the two treatments at 29 hospitals, are published in the April 10 issue of the *New England Journal of Medicine* by researchers from the University of Michigan Cardiovascular Center, Harvard University and others. The study was funded by Cordis, a Johnson & Johnson company, which had no role in the analysis of study data.

“Patients who are undergoing a procedure want to know that they’ll be protected long-term from stroke, and that the procedure is safe,” says Hitinder Gurm, M.D., the U-M interventional cardiologist who is the study’s first author. “This is the first study to suggest that stents do just as well long-term as surgery, in high-risk patients.”

The study’s senior and corresponding author is Donald Cutlip, M.D., executive director of clinical investigations at Harvard University’s Clinical Research Institute. SAPPHIRE was led by Jay Yadav, M.D., formerly at the Cleveland Clinic and now at Piedmont Hospital in Atlanta.

In all, 41 of the 143 patients who received carotid stents, and 45 of the 117 patients who had open surgery, suffered a heart attack or a stroke, or died, within the first three years. The two rates are statistically equivalent, showing no difference between the two treatments. About a third of those events were strokes, most of them minor.

The two procedures both aim to do the same thing: to reduce the chance that a patient will suffer a stroke because a blood clot forms in a narrowed, plaque-clogged carotid artery, and then travels to the brain.

Most people are familiar with the idea that clogged arteries near the heart can lead to a heart attack. But far fewer people know the risks related to carotid artery disease.

This is despite the fact that both heart (coronary) artery disease and carotid artery disease are caused by the same plaque-forming processes involving inflammation, cholesterol and genetics. Just as in the heart, most patients experience no symptoms from clogged carotids. As a result, many people don’t realize they have the disease until they suffer a stroke or mini-stroke.

As many as one in four American adults have some narrowing of the carotid arteries. About 5 percent of women over age 65 and a slightly higher percentage of men in the same age group have at least one carotid blockage that cuts off 50 percent of the opening through which blood can flow.

The greater the blockage, the higher the risk of stroke. People who have already had a stroke or mini-stroke that originated in their carotid arteries are at an extremely high risk of suffering another stroke, while those who have severe carotid blockages but no history of stroke have less risk.

Both groups of patients are often considered the best candidates for some sort of treatment, though Medicare will only cover stents for patients who have experienced symptoms of carotid artery disease. But the debate over whether surgery or stenting is best or safest has raged for years.

Stents, which are tiny wire-mesh tubes that can hold open a blocked carotid, have been seen as a less-invasive option, because they can be threaded up into the neck from a tiny incision in the arm or groin. But the stent procedure carries its own risk of stroke, unless a debris-catching device is deployed to intercept anything that breaks off from the wall of the artery while the procedure is under way. Such filters, called emboli protection devices, were used in the SAPPHIRE study.

Meanwhile, carotid endarterectomy operations have been performed tens of thousands of times each year for decades. The operation opens an incision in the neck below the jaw, allowing a surgeon to divert the blood flow temporarily while he or she opens the carotid and clears out the plaque. Sometimes a stretch of new blood vessel is sewn into place.

But as tried-and-true as the operation is, it can lead to complications

among people who have heart failure, lung disease, a history of neck surgery or radiation therapy – or who are over age 80 or have had previous carotid artery treatment but have developed new blockages.

Such patients are called high-risk, and stents have been seen as a lower-risk option for them. But until now, it was not known whether they would get the same stroke-preventing benefit from a stent.

In the SAPPHIRE study, patients who had symptoms of their carotid disease — such as a mini-stroke, stroke or dizziness — could participate if one of their carotids had a blockage of 50 percent or greater. But those without symptoms could only participate if they had a blockage of 80 percent or more that had been discovered through an exam such as an ultrasound scan of the neck.

In all, three-year data was available on 260 of the 334 patients who were randomly assigned to one of the two treatments at the beginning of the study. Previous analyses of SAPPHIRE data have shown no difference between the two treatment groups after 30 days and one year. The main measure to compare the two treatments was a combination of stroke, heart attack or death from any cause, though each type of incident was also analyzed.

“Clinical trials are now under way to determine the relative risks and benefits of stenting and endarterect-omy in average-surgical-risk patients, and to compare different stent procedures,” says Gurm, an assistant professor of internal medicine at the U-M Medical School and the VA Ann Arbor Healthcare Center. He notes that two such trials are under way at U-M. “Outside of trials, I do not think a person with average surgical risk should undergo stenting. But for high-risk patients, we can now be certain that they will have a similar long-term outcome from stenting as they would have had from surgery.”

Source: University of Michigan