Study Boosts Stents in Stroke Prevention

By THOMAS M. BURTON And JON KAMP

More people at risk of strokes may opt for metal stents to prop open their neck arteries instead of having more-invasive surgery, if results of a 10-year study persuade officials to make the stent procedure more widely eligible for Medicare reimbursement.

The study, which compared the two approaches for clearing fatty plaque from carotid arteries, concluded that stents and surgery were reasonably close in terms of safety and effectiveness. Results of the federally funded trial, called CREST, were made public Friday at a stroke-medicine meeting in San Antonio.

The stenting procedure, which is less invasive than surgery and usually involves a shorter hospital stay, has been restricted by the federal Medicare program to patients with previous stroke symptoms and who are at high surgical risk. Now, doctors and manufacturers are expected to make a concerted push to get Medicare to reimburse for stents in a far wider population. Abbott Laboratories, Johnson & Johnson, Boston Scientific Corp. and ev3 Inc. make the stents, which look like small tubular scaffolding.

"If you properly train to do this procedure, the two procedures are equal," said L. Nelson Hopkins, chairman of neurosurgery at the State University of New York at Buffalo and a key investigator in the study. Dr. Hopkins, who does both carotid surgery and stenting, has been an adviser to Abbott and received research support from J&J.

About half the patients in the 2,502-patient study had never suffered any symptoms, despite showing significant fatty-plaque blockage in their neck arteries. These patients, like those who had suffered previous mini-strokes, benefited about equally from stents and the surgery, known as carotid endarterectomy. About 30,000 carotid-stent placements occur in the U.S. annually, compared with more than 100,000 carotid operations.

It has been known for more than 15 years that well-performed carotid surgery can cut the risk of stroke and death by roughly half for people with major blockages in the carotid arteries supplying blood to the brain. But drug therapy, including the wide use of statins, has greatly improved since 1995, when the last landmark study of carotid surgery was performed. Many doctors now advise patients to get drug therapy only, avoiding both surgery and stents, if they don’t have symptoms.

As a result, the lead investigator of the CREST study, Thomas G. Brott, professor of neurology at the Mayo Clinic in Jacksonville, Fla., said he and colleagues were planning a new study that would compare all three approaches.

Complicating the picture was a European carotid stent/surgery study published in the British journal the Lancet almost simultaneously with CREST. That 1,713-patient research found a higher rate of stroke, death or heart attack among stent patients (8.5%), compared with surgery patients (5.2%), after four months.

However, various doctors said the European studies failed to include several backstops that boost the performance of stents, including standard drug therapy, higher training certification for doctors inserting the stents and the use of a tiny fishnet-like devices—called "embolic protection"—to catch plaque dislodged during
the stenting procedure. The plaque, if not caught, can cause the very strokes that doctors seek to avoid. London neurologist Martin M. Brown, primary investigator in the European study, didn't respond immediately to a request for comment.

Patients in CREST were observed for an average of 2.5 years, with some patients followed up to four years. The rate of short-term adverse events—stroke, heart attack or death—plus longer-term stroke was statistically the same in the stent patients (7.2%) as in the surgery patients (6.8%).

In the 30 days following the procedure, the heart-attack rate was higher in the surgical patients (2.3%) than in stented patients (1.1%). Conversely, the 30-day rate of stroke was higher in the stenting group, at 4.1%, than in the surgery patients, 2.3%. Dr. Brott said "patients' quality of life was impacted more by the strokes than by the heart attacks" one year after suffering those events. Still, the rates of complications were low, compared with those of similar studies in recent years.

Before patients consider either surgery or a stent, Dr. Hopkins said, the most important thing is to get a second opinion and an experienced doctor.