CAPTURE Shows Training Offsets Inexperience

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WASHINGTON — Participation in a training program on carotid stenting can offset interventionalist inexperience, judging from the early findings of a large postmarketing study of the procedure as performed in community settings, said Jay Yadav, M.D., at a symposium sponsored by the Cardiovascular Research Foundation.

The training program for physicians contributed to the procedure's success, said Dr. Yadav, head of vascular intervention at the Cleveland Clinic Foundation, who presented results on the first 1,603 patients in the Carotid RX Acculink/Accunet Post-Approval Trial to Uncover Unanticipated or Rare Events (CAPTURE) study.

The study, sponsored by Guidant Corp., aims to look at 2,500 patients in total. It was designed to determine whether stenting with Acculink/Accunet can be performed safely, to identify and catalog rare or unanticipated events with the devices, and to evaluate the training program.

The company agreed on the program's design in collaboration with the Food and Drug Administration and the Center for Medicare and Medicaid Services. CMS hoped to get more data on the procedure, especially in asymptomatic patients. The Acculink/Accunet system was approved in August 2004 for high-risk, symptomatic patients, but CMS agreed to reimburse hospitals participating in CAPTURE for procedures conducted on symptomatic and asymptomatic candidates, said Jim Neupert, vice president of marketing for Guidant Endovascular Solutions.

To enter the program, physicians must already have performed a certain number of procedures, he said. Training usually consists of 2 days of lectures and hands-on training using an anatomic model and simulator. Patients who participate in CAPTURE must be evaluated before enrollment, within 24 hours of the procedure, and 30 days postprocedure by an independent neurologist. They also have a 30-day follow-up visit with the interventionalist.

Most patients (74%) were seen by physicians with "medium" stenting experience—that is, they had conducted 10 or fewer carotid procedures as the primary operator. Ten percent of patients were seen by physicians who had conducted five procedures as the primary operator, using Acculink/Accunet, and 16% of patients were seen by physicians with "low" experience, which was defined as having conducted 25 carotid angiograms, 10 peripheral procedures with self-expanding stents, and 10 procedures with the 0.014-inch guidewire in the Acculink system.

Most patients (63%) were treated by interventional cardiologists, 20% by vascular surgeons or neurosurgeons, and 17% by an interventional radiologist or interventional neuroradiologist.

Mean patient age was 73 years; 81% were over age 65, and 24% were over age 80. Hypertension and hypercholesterolemia were seen in 80%-90% of patients. Of the asymptomatic patients, 90% had greater than 80% stenosis; 74% of symptomatic patients had that level.

The adverse event rate was similar to that in the pivotal approval study for these devices, the Acculink/Accunet for Revascularization of Carotids in High-Risk Patients (ARCHER) trial, said Dr. Yadav, who is on the study's executive committee and does not receive personal funding from Guidant.

Within 30 days of the procedure, the death rate in CAPTURE was 1.6% (with 1.1% deemed stroke-related), compared with 2.1% in the ARCHER trial. The stroke rate was 4% (vs. 6%), and the incidence of MI was 1% (vs. 2%).

At 5%, the stroke rate was similar in patients whose physicians had greater experience, compared with those whose physicians had medium (4%) or low (5%) experience. Dr. Yadav said age seemed to be an important variable, noting that patients over 80 years old had worse outcomes, but would still do better with stenting than with medical management.

The patients' ages and whether they were symptomatic interacted to affect mortality and morbidity. Within 30 days of the procedure, the death rate for symptomatic patients under age 80 was 2%, vs. 10% for the over-80 group. Of the symptomatic patients, 8 of the 48 octogenarians (17%) had a stroke, vs. 12 of the 108 patients younger than 80 (11%). The difference was not as striking in asymptomatic patients. Eleven (1%) under age 80 died within 30 days, vs. 7 (2%) of those over 80. There were 18 (6%) strokes in the over-80 group, vs. 27 (2%) in the under-80 group. ■

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