

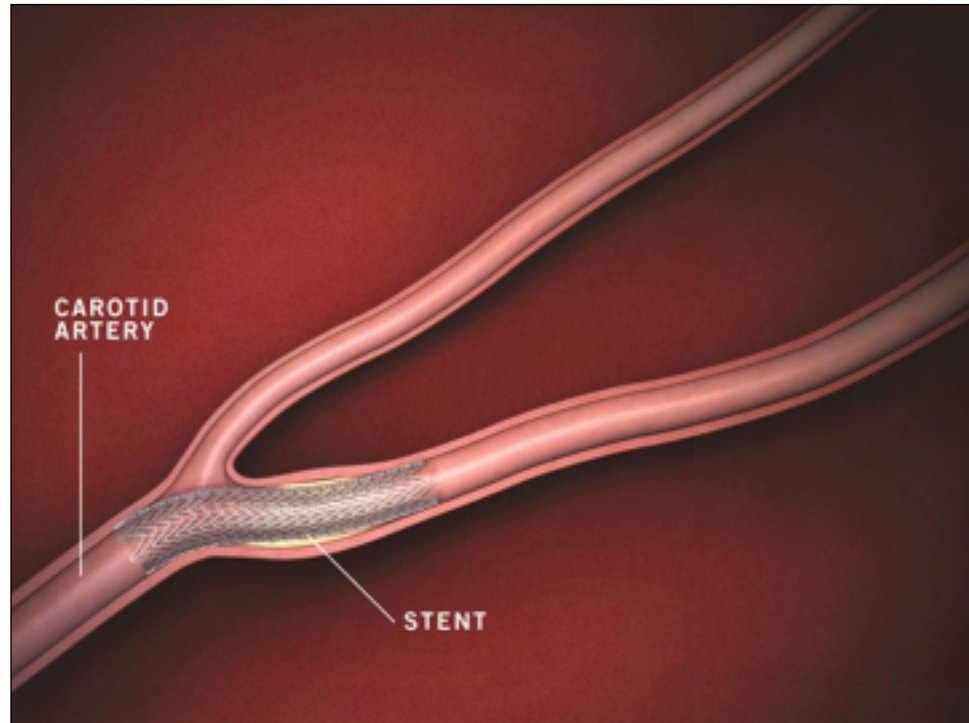
## CAPTURE: Carotid Stenting in the “Real World”

For patients at high risk of complications with standard surgical endarterectomy therapy, carotid stenting with distal embolic protection yields low event rates and low incidence of device failure, according to the results of CAPTURE (Carotid ACCULINK/ACCUNET Post Approval Trial to Uncover Rare Events).

Carotid artery disease accounts for about 25% of the strokes reported in the US, stated CAPTURE investigator William Gray, MD, associate professor of clinical medicine at Columbia University Medical Center. CAPTURE is a post-market FDA-mandated registry of the Guidant RX Acculink Carotid Stent System with the RX AccUNET Embolic Protection System. The purpose of which is to evaluate “real-world” use of the devices and to monitor malfunctions. The trial registry now includes 2500 patients enrolled at 188 centers treated by 240 physicians with moderate levels of experience. The primary endpoint is the composite of death, stroke or myocardial infarction (MI), at 30 days after stent placement Gray said.

The preliminary report of 1600 patients from CAPTURE presented at last year’s Transcatheter Cardiovascular Therapeutics meeting suggested that carotid artery stenting improves outcomes in this high-risk population of patients with plaque build-up in the arteries supplying blood to the brain. In this earlier analysis, the primary combined endpoint occurred in 5.7% of patients.

“A nearly 3% reduction in primary combined endpoint compares favorably to the 8.3% event rate in the pivotal nonrandomized ARCHER (ACCULINK for Revascularization of Carotids in High-Risk Patients) trial leading to FDA approval for the Guidant device,” Gray stated. This difference was primarily due to lower rate of myocardial infarction in asymptomatic lower risk patients. In addition it compares



favorably to the 14.5% event rate in high risk patients in the surgical trials. Asymptomatic patients appeared to benefit, with a combined 4.5% incident rate at 30 days and risk of stroke of 3.5%. Acceptable event rates for asymptomatic patients is under 3%. Risk for patients <80 years was 3.5%, a rate comparable to endarterectomy rates in low risk patients over the last decade. Risk for those 80 years was higher, but similar regardless of symptom status, Gray said. Patients with diabetes, smokers and females all had relatively low risk of stroke/death/MI. Low event rates were also in centers with low procedure volume.

Device malfunctions were few (0.2%), and none occurred after the filter was modified halfway through CAPTURE. Gray noted that while asymptomatic high-risk patients are not covered for carotid stenting under CMS (The Center for Medicare & Medicaid Services) he anticipates reassessment by CMS based on these results.

“The transfer of carotid stenting technology from clinical trial sites to clinical practice sites appears to have been successful with the same, or even better, outcomes in the clinical setting,” Gray concluded.