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Higher carotid arterial stenting rates associated with poorer clinical outcomes

Increase in adverse outcomes coincides with expanded Medicare coverage of procedure

PHILADELPHIA—Among eligible Medicare beneficiaries, increased use of carotid arterial stenting (CAS) procedures to treat carotid stenosis—the narrowing of the carotid artery—is associated with higher rates of mortality and adverse clinical outcomes, including heart attack and stroke, according to researchers from the University of Pennsylvania School of Medicine.

Published in the November 2009 issue of the *Journal of Vascular Surgery*, the study adds to a growing body of research about the effectiveness of stenting for preventing heart attack, stroke, and death. Findings lend further insight into factors influencing how medical technology performs when integrated as treatment among the general Medicare population as opposed to in a controlled clinical trial setting.

For treatment of moderate to severe carotid stenosis, CAS is an alternative to carotid endarterectomy (CEA), a surgical procedure that opens blocked arteries that supply the brain. Introduced in the 1990s, CAS was initially available to Medicare patients only when they were enrolled in clinical trials testing the effectiveness of the minimally invasive procedure. When Medicare expanded coverage of the procedure in 2005, the rate of CAS utilization nearly quadrupled—from 266 to 1,015 procedures per month—as the procedure was available for the first time to the general Medicare population, including elderly patients deemed too ill for surgery who would have had no other treatment option.

"Our study showed that in areas where CAS was used more commonly during the coverage era, the clinical outcomes from the combined population of CAS and CEA patients worsened. Nevertheless, stenting should remain a viable and effective treatment option that doctors and patients consider judiciously," says lead author Peter Groeneveld, MD, MS, assistant professor of medicine at the University of Pennsylvania School of Medicine. "CAS is often the only option

for patients who are not healthy enough to undergo surgery. However, this state of health may inevitably affect clinical outcomes from the procedure."

Using a national sample of 46,784 Medicare patients older than 66 years of age, the study examined clinical outcomes of both methods in the two 'eras' -- when CAS was covered only in clinical trials and after it became widely covered under Medicare. For each 'era,' researchers assessed clinical outcomes at 90 and 270 days after the procedure in patients who had received either procedure for the first time over a twelve-month period. Key findings showed that in geographic areas that widely adopted CAS during the coverage era, the rate of heart attack, stroke, and death was greater in the 90 and 270 days following the procedure than in the pre-coverage era.

"Key findings from the retrospective study included:

- When adjusted statistically, more 270-day adverse outcomes in the era of Medicare coverage.
- In geographic areas with higher adoption rates of CAS during the expanded coverage era, there was a higher rate of 90-day mortality and adverse outcomes, and a higher rate of 270-day mortality and adverse outcomes.
- No difference in mortality or adverse outcome rates between eras in locations with lower CAS adoption.

Groeneveld, who is also affiliated with the Philadelphia Veterans Affairs Medical Center, has researched the impact of cardiac devices, including drug-eluting stents and implantable cardioverter-defibrillators, for more than 15 years, notes that in a time of healthcare reform, clinical trials and comparative effectiveness research may influence policymakers' decisions about which procedures receive coverage. "Some procedures may receive coverage because clinical trials show them to be more effective, even if by a small percentage, than the current standard treatment. But that rate of effectiveness can change drastically as more patients with unique medical characteristics begin to receive the procedure, and as more doctors with varying skill levels perform it."

In the study, researchers used propensity scoring to match patients across eras and locations in order to reduce bias arising from variables such as sex, race, age, clinical comorbidities, and hospital characteristics, among others. The 'pre-coverage era' was defined as October 1, 2002, through September 30, 2004, and the 'coverage era' was defined as August 1, 2005, through

March 31, 2006, after the Centers for Medicare and Medicaid Services implemented a national coverage decision expanding patient eligibility criteria for CAS.

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PENN Medicine is a \$3.6 billion enterprise dedicated to the related missions of medical education, biomedical research, and excellence in patient care. PENN Medicine consists of the University of Pennsylvania School of Medicine (founded in 1765 as the nation's first medical school) and the University of Pennsylvania Health System.

Penn's School of Medicine is currently ranked #3 in the nation in U.S. News & World Report's survey of top research-oriented medical schools; and, according to the National Institutes of Health, received over \$366 million in NIH grants (excluding contracts) in the 2008 fiscal year. Supporting 1,700 fulltime faculty and 700 students, the School of Medicine is recognized worldwide for its superior education and training of the next generation of physician-scientists and leaders of academic medicine.

The University of Pennsylvania Health System (UPHS) includes its flagship hospital, the Hospital of the University of Pennsylvania, rated one of the nation's top ten "Honor Roll" hospitals by U.S. News & World Report; Pennsylvania Hospital, the nation's first hospital; and Penn Presbyterian Medical Center, named one of the nation's "100 Top Hospitals" for cardiovascular care by Thomson Reuters. In addition UPHS includes a primary-care provider network; a faculty practice plan; home care, hospice, and nursing home; three multispecialty satellite facilities; as well as the Penn Medicine at Rittenhouse campus, which offers comprehensive inpatient rehabilitation facilities and outpatient services in multiple specialties.
