

April 16, 2009

Stephen Phurrough, MD, MPA  
Director, Coverage and Analysis Group  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

*Electronically submitted to [steve.phurrough@cms.hhs.gov](mailto:steve.phurrough@cms.hhs.gov)*

**RE: Comments on Tracking Sheet for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R7)**

Dear Dr. Phurrough,

The Society of Interventional Radiology (SIR) is a physician association with over 4,300 members that represents the majority of practicing vascular and interventional radiologists in the United States.

The Society of Interventional Radiology previously stated (3/2/08) its support for wider reimbursement for carotid artery stenting (CAS) conditional on the unpublished acceptable outcomes from CAS registries being confirmed and **only if** facilities participate in a multispecialty accreditation program that requires facility outcomes to meet the AHA benchmarks as a condition for receiving and maintaining accreditation. Since the prior NCD, additional outcomes have been published. The registry data from CAPTURE 2 and EXACT have been published recently in *Circulation* (Gray et al), which has prompted the current re-opening of the NCD. In addition, data have been published comparing outcomes from CAS vs CEA (carotid endarterectomy) based on national hospital reported outcomes (McPhee et al) and based on the Society for Vascular Surgery Vascular Registry (Sidawy et al).

The article by Gray reports on over 6300 patients defined as high surgical risk, 90% of whom were asymptomatic, with outcomes assessed by an independent neurologic exam. Overall outcomes for asymptomatic patients with > 80% diameter stenosis and for symptomatic patients with > 50% diameter stenosis were within the American Heart Association (AHA) benchmarks of 3% and 6% 30 day combined stroke and death for patients < age 80. Stratification for high surgical risk based on anatomic vs physiologic factors for asymptomatic patients showed 30 day stroke/death outcomes of 2.7% vs 3.2%. Similar stratification for symptomatic patients showed 30 day stroke/death outcomes of 1.7% (small sample size) vs 6.4%.

The MCPhee article reports on nearly 136,000 patients treated with either CEA (90%) or CAS (10%) in 2005. There was no requirement for independent neurologic assessment for either procedure, so one would expect lower reported rates for stroke for both procedures but accurate reporting of death.

However, many of the patients treated with CAS were likely also included in one of the CAS registries that required independent neurologic examination, and, therefore, CAS reported stroke rates may be more accurate and higher than CEA reported stroke rates. In addition, the outcomes were reported based on events during the hospitalization rather than within 30 days, which will under report adverse outcomes by about 30% for CAS (Sidawy). Overall stroke rates for CAS vs CEA were 1.8% vs 1.1%. Overall death rates for CAS vs CEA were 1.1% vs 0.6%. For asymptomatic patients the stroke rates for CAS vs CEA were 1.6% vs 0.88% and the death rates were 0.57% vs 0.38% and for symptomatic patients the stroke rates for CAS vs CEA were 4.1 vs 2.5% and the death rates were 4.6% vs 1.4%. Due to the above mentioned factors (lack of independent neurologic exam and outcomes from time of discharge) the data cannot be compared to the AHA benchmarks, but the outcomes of CAS vs CEA can be compared and indicate that CAS has roughly twice the morbidity compared to CEA regardless of preoperative medical co-morbidities.

The Sidawy article reports on registry data from 6403 carotid revascularizations nearly evenly split between CAS and CEA. The combined outcome of death/stroke/MI at 30 days for symptomatic patients was 7.13% vs 3.75% for CAS vs CEA. For asymptomatic patients the combined outcome for CAS vs CEA was 4.6% vs 1.97%. For carotid stenosis secondary to atherosclerotic disease the combined outcome for CAS vs CEA was 6.42% vs 2.62%. The outcome of death (which will be unaffected by use of independent neurologic evaluation) was 2.07% for CAS vs 0.73% for CEA. Differences between CAS and CEA remained significant although with slightly lower odds ratios when the data was adjusted for greater co-morbidities in the CAS group. Death and stroke remained approximately twice as likely following CAS vs CEA. Since independent neurologic assessment was not required in the SVS registry, these reported outcomes for stroke are likely underestimated (again, particularly for CEA) compared to the Gray article but are relevant for comparison with AHA benchmarks for stroke/death. However, Sidawy does not report combined stroke and death without also including MI.

The Gray data is the most rigorous, but it is concerning that asymptomatic patients with atherosclerotic disease (high risk based on physiologic rather than anatomic factors) have a 3.2% stroke and death rate and this rate is likely even higher since Gray reports that patients in EXACT did not have carotid restenosis as a data element for anatomic risk and these patients were included in the physiologic risk group. The data from McPhee and Sidawy are concerning for the significantly worse outcomes from CAS vs CEA and the possibility that, for CAS, outcomes outside of the trial setting may be less likely to meet the AHA benchmarks.

Based on the above data and concerns, SIR supports expanded reimbursement for CAS only for asymptomatic patients < age 80 with stenosis > 80% diameter for patients considered high surgical risk based on anatomic factors, but, again, **only if** facilities participate in a multispecialty accreditation program that requires facility outcomes to meet the AHA benchmarks as a condition for receiving and maintaining accreditation. Such an accreditation program does not yet exist but such a program is currently being written by a group representing the American Academy of Neurology, the American Association of Neurological Surgeons and the Congress of Neurological Surgeons, the American Society of Neuroradiology, the Neurocritical Care Society, the Society of NeuroInterventional Surgery, the Society of Interventional Radiology, the Society of NeuroInterventional Surgery, and the Society for Vascular Surgery. Participation in national CAS registries is necessary but insufficient, since participation does not require that outcomes meet an acceptable benchmark. It is hoped that the accreditation program will become available in a time frame that matches the decision making of CMS to provide expanded reimbursement.

We support the following definitions for anatomic factors that lead to high surgical risk:

1. Previous carotid endarterectomy or carotid stent with recurrent stenosis
2. Prior radiation therapy
3. Prior radical surgery to the ipsilateral neck
4. Surgically inaccessible lesion above C-2 or a common carotid artery lesion below the clavicle)
5. Contralateral vocal cord palsy
6. Presence of tracheostomy
7. Contralateral internal carotid artery occlusion

We do not support reimbursement for asymptomatic patients at high surgical risk based on physiologic factors. The data from Gray indicate a stroke/death rate above 3%. In addition, asymptomatic patients with high physiological risk should have a good 5 year life expectancy if any benefit from CAS is to be demonstrated. The recently reported 3 year follow-up in SAPPHIRE raises serious questions about the 5 year survival rate in asymptomatic high physiological risk patients. In SAPPHIRE most of the increase in major adverse events between 1 and 3 years was accounted for by deaths, the majority of which were from non-neurologic causes. Rates of death were approximately 7 to 8% per year, with an extrapolated rate of death at 5 years of 28% (upper bound of the 95% confidence interval, 42%) for patients who underwent stenting and 35% (upper bound of the 95% confidence interval, 48%) for those who underwent endarterectomy. It therefore remains unclear that either CAS or CEA is better than best medical therapy in asymptomatic high physiological risk patients.

SIR supports the continued need for independent neurological assessment pre and post procedure.

SIR supports reimbursement for CAS procedures performed without embolic protection if the use of an embolic protection device (EPD) was felt unsafe or technically not possible. We agree that the use of an EPD is optimal and probably (although not definitely) reduces the risk of stroke as a complication of CAS. However, in a small percentage of cases the device cannot be safely deployed. Since the prior NCD two published articles challenge the effectiveness of embolic protection devices. Barbato et al reported a randomized trial of CAS 71 patients with and without embolic protection. There were new MRI lesions in 72% of the patients treated with EPD compared to 44% in the no protection group. Perona et al published a retrospective analysis of 400 patients (61% symptomatic) treated with CAS without EPD with a 30 day stroke/death rate of 2.3% as determined by independent neurologist evaluation. These outcomes rival the best outcomes reported for CAS performed with EPD. We believe that physicians will use their best judgment to abort those procedures where an EPD is felt necessary to reduce stroke risk and continue with those procedures in which the risk of embolization is felt to be low (such as restenosis due to intimal hyperplasia post endarterectomy). Linking acceptable outcomes to accreditation will be further incentive to physicians to use, or not use, an EPD appropriately. In previous letters to CMS the SIR, the NeuroVascular coalition, vascular surgery, and cardiology have all supported the recommendation to allow payment for CAS procedures in which an EPD cannot be safely used.

We thank CMS for consideration of expanded reimbursement for CAS. In summary,

1. We support expanded reimbursement for asymptomatic high surgical risk patients based on anatomic factors and with stenosis > 80% diameter but **only if** it is required that facilities participate in a multispecialty accreditation program that requires that outcomes meet national benchmarks.

2. We do not support expanded reimbursement for asymptomatic patients considered high surgical risk based on physiologic factors.
3. We support reimbursement for CAS procedures performed without embolic protection if the use of an embolic protection device (EPD) was felt unsafe or technically not possible.
4. We support the use of independent neurological assessment pre and post procedure.

Thank you again for the opportunity to submit these comments. If we can provide any additional information or if you have any questions, please do not hesitate to contact me at (401) 456-2204 or Tricia McClenny, SIR's Associate Executive Director, at (703) 691-1805 or [tricia@sirweb.org](mailto:tricia@sirweb.org).

Sincerely yours,



Brian F. Stainken, MD, FSIR  
President, Society of Interventional Radiology

cc: Sarah McClain, MHS  
Joseph Chin, MD  
David Sacks, MD, FSIR

References:

1. Gray WA, Chaturvedi S, Verta P. 30-Day Outcomes for Carotid Artery Stenting in 6,320 Patients from Two Prospective Multicenter, High Surgical Risk Registries. *Circ Cardiovasc Intervent* published online Mar 6, 2009
2. McPhee JT, Schanzer A, Messina LM, Eslami MH. Carotid artery stenting has increased rates of postprocedure stroke, death, and resource utilization than does carotid endarterectomy in the United States, 2005. *J Vasc Surg* 2008;48:1442-1450
3. Sidawy AN, Zwolak RM, White RA, Siami FS, Schermerhorn ML, Sicard GA. Risk-adjusted 30-day outcomes of carotid stenting and endarterectomy: Results from the SVS Vascular Registry. *J Vasc Surg* 2009;49:71-79
4. Barbato JE, Killavou E, Horowitz MB, et al. A randomized trial of carotid artery stenting with and without cerebral protection. *J Vasc Surg* 2008;47:760-765
5. Perona F, Castellazzi G, Valvassori L, et al. Safety of Unprotected Carotid Artery Stent Placement in Symptomatic and Asymptomatic Patients: A Retrospective Analysis of 30-day Combined Adverse Outcomes. *Radiology* 2009;250:178-183