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Carotid Artery Stenting

Payment, Politics, and Equipose*

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In the 1990s, Food and Drug Administration (FDA) approval for new devices for coronary and peripheral revascularization was a necessary and sufficient requisite for reimbursement from the Centers for Medicare and Medicaid Services (CMS). However, in the new millennium, FDA approval is necessary, but not sufficient, for CMS reimbursement, an issue that has become strikingly apparent with regard to carotid artery stenting (CAS). Under the current national coverage determination (NCD) policy, there is CMS payment for CAS in symptomatic patients with carotid stenosis >70% who are high risk for carotid endarterectomy (CEA), using FDA-approved CAS systems in CMS-approved institutions. The NCD policy requires the use of approved embolic protection devices (EPD) (no payment if an EPD is not used), predefined criteria for performance of CAS procedures that are consistent with professional societal guidelines, and independent neurological assessment. The NCD policy also allows payment for high-risk patients who are enrolled in Category B Investigational Device Exemption (IDE) trials or post-approval registries, as long as patients have symptomatic stenosis ≥50% or asymptomatic stenosis ≥80%. The NCD policy does not cover CAS in any standard-risk patients; there are no restrictions for CEA reimbursement.

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In this issue of the *Journal*, Bijuklic et al. (1) performed a small randomized clinical trial (RCT) that demonstrated that CAS with proximal EPD provides better cerebral protection than distal EPD, based on quantitative brain diffusion-weighted magnetic resonance imaging. Although the study was not powered to evaluate the risk of stroke, the findings are similar to another RCT, which reported less cerebral embolization by transcranial Doppler with proximal EPD compared with distal EPD (2). These data are sensible, since in contrast to distal EPDs, proximal EPDs provide embolic protection prior to crossing the target lesion with a guidewire, and should be more efficient at capturing and removing debris since they are not dependent on filter pore size or particle dimensions. The findings of both studies add further incremental understanding of CAS technique, but are they likely to influence CMS reimbursement?

The lack of equipoise in CMS payment for CEA and CAS is influenced by several factors. Professional societies insist on adherence to the American Heart Association/American Stroke Association benchmarks of 3% and 6% for the 30-day risk of death and stroke for asymptomatic and symptomatic patients, respectively (3). Some experts suggest that European RCTs of CEA and CAS showed unequivocal superiority of CEA (4–6). However, these trials are invalid by today's standards of operator experience, dual antiplatelet therapy, and EPDs, and did not meet CMS NCD standards. Others refute the conclusions of the CREST (Carotid Revascularization Endarterectomy versus Stenting Trial) (7), arguing that equivalence of CEA and CAS should not be based on a composite endpoint of death, stroke, and myocardial infarction (MI) at 30 days. Finally, many physicians express sentiments that patients with asymptomatic carotid stenosis should be treated with optimal medical therapy alone, even though optimal therapy has not been defined, and the impact on patients with carotid stenosis has not been studied.

Because 70% of CAS procedures are performed by interventional cardiologists, there is concern among our professional societies that some physicians advocate against expansion of CMS coverage to protect their turf. In the minds of advocates for expansion of coverage, this political viewpoint seems to be supported by the failure of CMS to modify its NCD policy, despite mounting evidence to do so. Is it not reasonable for CMS to reconsider its NCD policy since there is nearly a decade of CAS experience performed in accordance with societal guidelines and CMS NCD policy?

So, what is this evidence and where do we begin? There is a historical divide in CAS studies in the United States before and after the SAPPHIRE (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy) trial, which set important standards for the definition of high-risk and standard-risk patients; routine use of EPD and dual antiplatelet therapy; and independent neurological assessment, data collection, and data analysis (8). In aggre-

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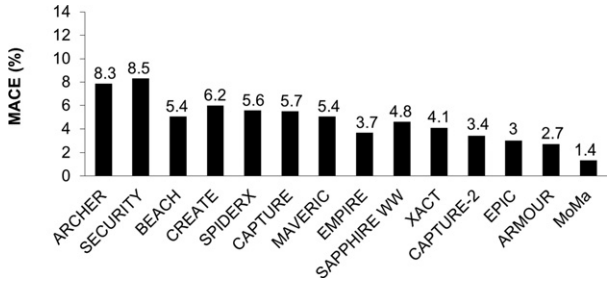

Figure 1 MACE at 30 Days After CAS in High-Risk Studies

See Safian (10) for study eponyms and citations. The EMPIRE (Embolic Protection with Reverse Flow), ARMOUR (ProximAl PRotection with the MOMA Device DUring CaRotid Stenting), and MoMa studies utilized proximal embolic protection, whereas other studies utilized distal embolic protection. CAS = carotid artery stenting; MACE = major adverse cardiovascular events.

gate, current CAS experience is represented by published data in more than 5,000 high-risk and 2,000 standard-risk patients. In SAPPHIRE, there was a strong trend favoring the safety of CAS in high-risk patients by virtue of a lower risk of major adverse cardiovascular events (MACE) at 30 days (death, stroke, MI) (8); outcomes for CAS and CEA were similar at 3 years (9). In the high-risk IDE and registry studies, there has been a dramatic decline in 30-day MACE from >8% in the early experience to <2% in recent experience (Fig. 1) (10). In standard-risk patients in CREST, 30-day MACE was similar; significant differences at 30 days included a higher risk of minor stroke after CAS, a higher risk of MI after CEA, and a higher risk of cranial nerve injury after CEA (7). Although differences in secondary endpoints have ignited more debate about CEA and CAS, the following points are crucial: First, event-free survival at 4 years was >95% in both groups, consistent with superb outcomes; second, 30-day MACE was similar for CEA and CAS in symptomatic and asymptomatic patients; and third, there were no major strokes or deaths at 30 days after CAS in the last 2 years of enrollment (W. Gray, personal communication, November 2011).

Taken together, it appears that current CAS outcomes in all patients satisfy the American Heart Association/American Stroke Association benchmarks. When considering central and cranial nerve injury, CAS is at least as safe as CEA, and the risk of MI is lower after CAS. The continued decline in 30-day MACE after CAS is attributable to improvements in technology, technique, patient selection, and operator experience, including the use of proximal EPDs; imaging studies suggest less intracranial embolization with proximal EPDs than distal EPDs, although the risk of stroke is low with both techniques. Carotid revascularization for symptomatic stenosis >50% and asymptomatic stenosis >70% is the current standard of care according to major professional societies, and is safely performed by CEA and CAS (3); further CAS trials are not needed to support reimbursement. It is time for CMS to align with professional guidelines, and establish equipoise for CEA and CAS.

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