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Review

Why the United States Center for Medicare and Medicaid Services (CMS) should not extend reimbursement indications for carotid artery angioplasty/stenting

Keywords
Carotid angioplasty, carotid endarterectomy, carotid stenting, carotid surgery, health economics, public health, vascular disease medical intervention.

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Abstract

In recent years, many important discoveries have been made to challenge current policy, guidelines, and practice regarding how best to prevent stroke associated with atherosclerotic stenosis of the origin of the internal carotid artery. The United States Center for Medicare and Medicaid Services (CMS), for instance, is calling for expert advice as to whether its current policies should be modified. Using a thorough review of literature, 41 leading academic stroke-prevention clinicians from the United States and other countries, have united to advise CMS not to extend current reimbursement indications for carotid angioplasty/stenting (CAS) to patients with asymptomatic carotid stenosis or to patients with symptomatic carotid stenosis considered to be at "low or standard risk from carotid endarterectomy (CEA)." It was concluded that such expansion of reimbursement indications would have disastrous health and economic consequences for the United States and any other country that may follow such inappropriate action. This was an international effort because the experts to best advise CMS are relatively few and scattered around the world. In addition, US health policy, practice, and research have tended to have strong influences on other countries.

A potential crisis looms in the United States–related to the proposal for the US Center for Medicare and Medicaid Services (CMS) to allow wider indications for government reimbursement for carotid angioplasty/stenting (CAS). We are writing to advise CMS to reject this proposal based on overwhelming evidence that it would have serious negative health and economic repercussions for the United States and any other country that may follow such inappropriate action. The purpose of this message is not to advise on existing CMS policy. Instead, we wish to advise that current Medicare coverage for CAS should not be extended to routine practice management of asymptomatic carotid stenosis or symptomatic carotid stenosis where the patient is considered at "low/average risk" of complications from carotid endarterectomy (CEA). We understand that, currently, CMS covers the cost of CAS for the indications listed below (the National Coverage Determination [NCD] for Percutaneous Transluminal Angioplasty [PTA] March 05, 2010):

(1) Concurrent with carotid stent placement when furnished in accordance with the FDA-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials.

(2) Concurrent with the placement of an FDA-approved carotid stent and an FDA-approved or -cleared embolic protection device for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing postapproval studies.

(3) Concurrent with the placement of an FDA-approved carotid stent with an FDA-approved or -cleared embolic protection device for the patients who are at high risk for CEA and who also have symptomatic carotid artery stenosis more than 70%.

(4) Patients who are at high risk for CEA and have symptomatic carotid artery stenosis of 50–70%, in accordance with the Category B IDE clinical trials or in accordance with the NCD on carotid artery stenting postapproval studies.

(5) Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis more than 80%, in accordance with the Category B IDE clinical trials regulation or in accordance with the NCD on CAS postapproval studies.

According to the same NCD, patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), so that they would be considered poor candidates for CEA. Significant comorbid conditions include but are not limited to the following:

(**1**) Congestive heart failure (CHF) class III/IV;
(**2**) Left ventricular ejection fraction (LVEF) < 30%;
(**3**) Unstable angina;
(**4**) Contralateral carotid occlusion;
(**5**) Recent myocardial infarction (MI);
(**6**) Previous CEA with recurrent stenosis;
(**7**) Prior radiation treatment to the neck; and
(**8**) Other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

Over the last two to three years the available evidence to direct current best stroke-prevention management of carotid stenosis has been reviewed by a number of leading academic clinicians. Current routine practice management of carotid stenosis is based on results of randomized trials of medical (noninvasive) intervention alone versus additional CEA for patients with symptomatic (Mayberg et al. 1991; North American Symptomatic Carotid Endarterectomy Trial Collaborators 1991; The European Carotid Surgery Trialists Collaborative Group 1998) or asymptomatic (Hobson et al. 1993; Executive Committee for the Asymptomatic Carotid Atherosclerosis Study 1995; Halliday et al. 2004; 2010) carotid stenosis. In these trials patients were randomized up to 30 years ago (1981–1994 and 1983–2003, respectively). Overall, an average annual stroke-prevention benefit of about 3.0% was measured for operated patients with moderate or severe (70–99% NASCET equivalent) symptomatic (Rerkasem and Rothwell 2011) carotid stenosis and about 0.5–1% for operated patients with moderate or severe (50–99% NASCET equivalent) asymptomatic (Chambers and Donnan 2005; Halliday et al. 2010) carotid stenosis compared to patients who received medical intervention alone. More recently, trials of CAS versus CEA (without a medical intervention-only-arm) were performed demonstrating that the perioperative stroke risk is twice about as high with stenting when compared with CEA (see below). These trials were most likely designed assuming medical intervention has not changed since the randomized surgical trials, aiming to find at least an equivalent CEA stroke-prevention benefit. However, it is now clear that the stroke-prevention efficacy of medical intervention has steadily and significantly improved over the last 30 years and continues to improve (Abbott 2009; Naylor et al. 2009; Abbott 2010; Naylor 2011; Spence et al. 2010), consistent with other observed falls in risk of stroke (Rothwell et al. 2004; Broderick 2011; Chimowitz et al. 2011), heart attack, and sudden death (Unal et al. 2005). Currently used benchmarks for a stroke-prevention benefit from CEA over medical intervention (a 30-day procedural risk of stroke/death of 3% for asymptomatic carotid stenosis [Goldstein et al. 2011] or 6% for symptomatic carotid stenosis [Furie et al. 2011]) are outdated. Therefore, the demonstration of stroke-prevention equivalence between CAS and CEA using these benchmarks (even if this had been achieved) would be insufficient to justify a current, routine practice indication for CAS.

The inappropriateness of the recent push for widening CMS coverage for carotid stenting is particularly evident with respect to asymptomatic carotid stenosis because the randomized surgical trial stroke-prevention benefit from CEA was so small and conditional. However, the most recent standardized measurements of the average annual rate of ipsilateral stroke among patients receiving medical intervention alone approximate only 0.5% (Goessens et al. 2007; Abbott 2010; Markus et al. 2010; Marquardt et al. 2010). This is about three times lower than for randomized surgical trial CEA patients (Executive Committee for the Asymptomatic Carotid Atherosclerosis Study 1995), about five times lower than randomized surgical trial nonoperated patients (Executive Committee for the Asymptomatic Carotid Atherosclerosis Study 1995), three times lower than CREST stented patients (Brott et al. 2010), and about half the rate of CREST CEA patients (Abbott 2009, 2010; Brott et al. 2010). The push for routine practice stenting for asymptomatic carotid stenosis is based largely on the recently published CREST results (Brott et al. 2010), and perhaps other clearly flawed randomized data (Brooks et al. 2004; Yadav et al. 2004), comparing CEA with CAS (without a medical intervention-only-arm) and implications of "equivalence" with CEA (Brott et al. 2011). As mentioned, such equivalence, even if supported by the data, would not be sufficient to justify a current, routine practice indication for CAS for asymptomatic carotid stenosis.

However, to add insult to injury, an equivalent stroke-prevention benefit between CAS and CEA has not been demonstrated. CAS in CREST (Brott et al. 2010), large registries, and population-based studies (Sidawy et al. 2009; Giles et al. 2010; Rockman et al. 2011), has been associated with about double the peri-procedural rate of stroke or death compared to CEA. Further, in CREST, among asymptomatic patients, the rate of peri-procedural stroke/death or later ipsilateral stroke projected to four years was 4.5% for 594 patients who had CAS and 2.7% for the 587 who had CEA (67% higher, $P = 0.07$). This outcome measure reached statistical significance when symptomatic patients were added (6.4% vs. 4.7%, 36% higher, $P = 0.03$). The inclusion of higher risk symptomatic patients, and larger sample sizes, allows easier detection of statistically significant differences. Supporters of routine CAS for asymptomatic carotid stenosis have tried to use a higher incidence of peri-procedural myocardial infarction (including minor infarction) associated with CEA to justify a higher stroke/death risk with CAS

(Blackshear et al. 2011). However, this is invalid and distracting because the aim of invasive carotid intervention is to prevent stroke. Further, in CREST, at least, a larger proportion of patients who suffered peri-procedural myocardial infarction associated with CAS (compared to CEA) died during follow-up (Naylor 2012a). More importantly, procedure-associated myocardial damage would be prevented entirely if unnecessary CEA and CAS interventions were not performed in the first place. In addition, it should also be noted that CAS has higher procedural costs compared to CEA (Paraskevas et al. 2011b).

The current situation regarding CEA and CAS for patients with asymptomatic stenosis in the United States is unjustified and outdated. Up to about 90–95% of these procedures are being performed for asymptomatic carotid stenosis (Hertzer 2011; Rockman et al. 2011), exposing patients to unnecessary risk and causing unjustified expenditure of at least one to two billion US health care dollars each year (Abbott 2009; Naylor et al., 2009; Hankey 2010; Bell 2011; Naylor 2012b; Spence and Veith 2011) at a time when health care costs need to be justified (Redberg 2011). Despite no previous CMS coverage for routine practice CAS for asymptomatic carotid stenosis, rates of CAS procedures are increasing dramatically, especially among cardiologists (Berkowitz and Redberg 2011; Nallamothu et al. 2011). Extending the approved indications for CAS will open the floodgates for widespread CAS and expose patients to unnecessary risk and greatly increase unjustified health expenditure (Paraskevas et al. 2011b).

Broadening the indications for CAS reimbursement for symptomatic carotid stenosis is also inappropriate. The request for such broadening of reimbursement will, once again, be based on the CREST trial conclusions (Brott et al. 2010) and the recently published American Heart Association (AHA) Guideline (approved by 13 other organizations) (Brott et al. 2011), which states that "CAS is an alternative to CEA for the treatment of symptomatic carotid stenosis. . ." Equivalence of the two procedures is implied (Paraskevas et al. 2011c, d). Unfortunately, the actual CREST data (Silver et al. 2011), most other randomized trial data (Mas et al. 2006, 2008; Ederle et al. 2010), meta-analyses (Bonati et al. 2010a; Economopoulos et al. 2011), and registry data (Sidawy et al. 2009; Giles et al. 2010; Rockman et al. 2011) do not justify this presumed equivalence of CAS and CEA for symptomatic carotid stenosis (Carotid Stenting Guidelines Committee 2011; Paraskevas et al. 2011a). In symptomatic patients, CAS, overall, is associated with about double the 30-day, 120-day, 6-month, and/or 4-year risk of stroke (or death) compared to CEA. The excessive CAS procedural risk of stroke or death is particularly notable in patients over 70 years of age (Bonati and Fraedrich 2011), yet not confined to the oldest age groups (Silver et al. 2011). CAS is also associated with a much higher peri-procedural risk of brain-imaging detected ischemic lesions than CEA (Bonati et al. 2010b) and a higher incidence of carotid restenosis (Eckstein et al. 2008; Bonati et al. 2009; Arquizan et al. 2011). No studies have shown CAS is better than CEA in preventing stroke in patients with symptomatic carotid stenosis and procedural costs are significantly higher with CAS (Paraskevas et al. 2011b). Thus, the extension of Medicare reimbursement to routine treatment for "low" and "standard" CEA-risk patients with symptomatic carotid stenosis is not currently justified.

Thus, in summary, at this time, the evidence does not support broadening reimbursement for CAS to routine management of patients with asymptomatic carotid stenosis or patients with symptomatic carotid stenosis considered at "low or standard" risk from CEA. It is acknowledged that this situation may change in the future.

Conflict of Interest

None.

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