



The Society for Cardiovascular  
Angiography and Interventions



AMERICAN  
COLLEGE of  
CARDIOLOGY

June 15, 2009

California Technology Assessment Forum

50 Beale Street  
San Francisco, CA 94105

Dear Forum Members:

The Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and the American College of Cardiology are responding to the California Technology Assessment Forum's draft assessment of Carotid Artery Stenting which was posted on your web site on June 10, 2009. We appreciate that you are allowing us to provide written comments even though your meeting is just 2 days away.

The Society for Cardiovascular Angiography and Interventions (SCAI) is a professional association representing over 4,000 invasive and interventional cardiologists. SCAI promotes excellence in cardiac catheterization, angiography, and interventional cardiology through physician education and representation, and quality initiatives to enhance patient care.

The Society for Vascular Medicine's mission is to promote vascular medicine through education, training and research.

The ACC is a 37,000 member non-profit professional medical society and teaching institution whose purpose is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, and leadership in the development of standards and formulation of health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

### **Introduction**

We believe the draft assessment does not address the key clinical issue in the assessment of carotid artery stenting (CAS) and that its findings are based on an inaccurate presentation of the evidence.

The California Technology Assessment Forum's (CATF) draft assessment of carotid artery stenting (CAS) is unnecessarily and inappropriately broad. The key clinical issue at this point in time is not whether CAS should be a treatment option for all patients with carotid artery stenosis but whether it is an appropriate treatment option for patients considered to be at increased risk for carotid endarterectomy (CEA) with symptomatic lesions  $\geq 50\%$  stenosis and asymptomatic lesions  $\geq 80\%$  stenosis, both consistent with U.S. Food and Drug Administration (FDA) approved labeling of seven CAS systems. The federal agency charged with determining and monitoring safety and efficacy of medical devices, the FDA, has found these devices "safe and effective" and permits marketing and sale of these devices for this indication.

The application of CAS systems for the prevention of stroke in average risk CEA patients is currently under

investigation in several trials. Currently, there is conflicting evidence regarding CAS safety and efficacy in this population. We await the results of both the CREST and the ACT-1 ongoing trials for more evidence in determining the utility of CAS in this patient subset.

There are several areas in the California Technology Assessment Forum's (CTAF) report on CAS where there appears to be misunderstanding of the published and peer-reviewed data that we would like to correct. Our organizations emphasize that when performing any comparison of carotid revascularization techniques it is essential to:

1. Specifically describe the population being treated including the patients with anatomic or comorbid features that increase their risk for conventional CEA, and whether the patients are symptomatic from their carotid atherosclerosis.
2. Require independent assessment of neurological outcomes using the National Institute of Health Stroke Scale (NIHSS).

CTAF should be aware that an interdisciplinary group of professional societies (SCAI, ASA, AHA, ACC, AANN, AANS, ACEP, ACR, CNS, SAI, SIR, SNIS, SVM, and SVS) are preparing to publish a new guideline document entitled "2009 Guideline on the Management of Patients with Extracranial Carotid and Vertebral Disease (ECVD)". This guideline will take into account the evidence base available and provide evidence-based recommendations for the management of patients with carotid and vertebral artery disease. In the interest of minimizing confusion for patients, the medical community, and other payers, we would hope for some consistency with the recommendations provided in the ECVD Guideline.

In the draft assessment's introduction, specific concerns are cited regarding the over-representation of early stroke complicating CAS compared to CEA which are reported from national databases dependent on ICD-9 coding.<sup>1,2</sup> Both references cited were methodologically flawed due to self-reported outcomes data that were not audited for accuracy or were independent neurologic evaluations performed consistently. Self-reported outcomes and lack of neurological oversight are well documented causes of significant "heterogeneity" in outcomes<sup>3</sup>. There was asymmetry for CAS and CEA outcomes regarding independent neurological assessment. Most of the CAS patients were in clinical trials for reimbursement purposes that require an independent neurological examination, while most patients undergoing CEA did not receive independent neurological assessment. The combination raises the rate of detected complications (particularly minor stroke) in CAS, while under-reporting complications for CEA. The CAS and CEA patient groups were not clinically comparable either. CAS patients were older and sicker. In order to qualify for CMS reimbursement they were at increased surgical risk with medical comorbidities that would not be present in the routine CEA patients. Finally, in the only randomized controlled trial (RCT) in high surgical risk patients comparing the two therapies, there was no increased early stroke rate<sup>4</sup>.

Also within the introduction, the CTAF draft assessment discusses the poor performance of CAS compared to CEA in two European RCTs, in low or average risk surgical patients<sup>5,6,7,8,9</sup>. Despite debate regarding these outcomes, this review should be focused on the FDA approved label indications for CAS that is restricted to high surgical risk patients. The Stent Protected Angioplasty versus Carotid Endarterectomy (SPACE) study actually demonstrated superior (log rank  $p = 0.001$ ) outcomes for CAS compared to CEA for patients  $\leq 68$  years old.<sup>8</sup> This trial was stopped because they lacked funding to enroll enough patients to prove "non-inferiority"<sup>9</sup>. The second European trial (EVA-3S) was seriously flawed with inconsistent use of emboli protection devices, inadequate antiplatelet therapy and inclusion of inexperienced stent operators<sup>10</sup>.

On page 2 of the draft CTAF document, it is noted that in patients with symptomatic, severe (>70%) internal carotid artery stenosis, two large randomized clinical trials have demonstrated that carotid endarterectomy is more

beneficial than medical (aspirin) therapy in reducing the risk of stroke, but the reviewer failed to mention that both of these trials, in symptomatic patients, had 30 day stroke and death rates above 6%, the level set by the American Heart Association's Expert consensus committee to ensure clinical benefit in symptomatic patients undergoing CEA. It appears that the largest RCT comparing CEA to medical therapy, the Asymptomatic Carotid Surgery Trial (ACST)<sup>11</sup> has been left out of the review, while the smaller Asymptomatic Carotid Atherosclerosis Study (ACAS) trial was discussed<sup>12</sup>.

On page 3 of the draft CTAF assessment, an incorrect statement is made regarding catheter-based therapy of the carotid artery, suggesting that combining a stent with balloon angioplasty is intended "to prevent plaque rupture, arterial dissection and acute occlusion of the blood vessel". This is not true. Stents prevent elastic recoil and are effective in maintaining the vascular lumen after balloon dilation of an atherosclerotic plaque. Stents scaffold the artery to provide luminal support to maintain blood flow and patency, but have nothing to do with the prevention of plaque rupture at all.

**TA Criterion 1: The technology must have the appropriate regulatory approval.**

As discussed in the review, there are currently seven carotid stent systems (stent plus embolic protection system) approved by the FDA for sale in the US. These systems have all satisfied the federal regulatory requirements for "safety and efficacy" in symptomatic (>50%) and asymptomatic (>80%) high surgical risk patients.

The Center for Medicare and Medicaid Services (CMS) currently finds that CAS in symptomatic patients with  $\geq 70\%$  stenosis who are at increased risk for surgical complications is "reasonable and necessary" to prevent stroke. CMS also currently reimburses for high surgical risk patients with symptomatic carotid disease  $\geq 50\%$  and asymptomatic disease  $>70\%$  if patients are participating in an FDA sponsored clinical trial. Finally, CMS is currently considering expansion of their coverage decision, based upon recently published evidence (SAPPHIRE WW, CAPTURE-2, and EXACT) in more than 8,000 high surgical risk symptomatic and asymptomatic patients to be consistent with the FDA labeling indication for the CAS systems<sup>13,14</sup>.

**We concur that TA Criterion 1 has been met for patients at increased surgical risk for CEA.**

**TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.**

The American Heart Association's Expert Consensus panel has determined that if carotid revascularization can be done safely, with 30-day stroke and death rates  $\leq 6\%$  for symptomatic patients and a  $\leq 3\%$  for asymptomatic patients, it is a reasonable option for revascularization<sup>15,16</sup>. It is inappropriate to confine any analysis on the utility of CAS to only randomized trials. There has been only one RCT in high surgical risk patients, while thousands of patients have been treated in well controlled registry trials supporting pre-market approval applications for devices with the FDA<sup>17,18,19,20,21,22,23</sup>. It is not appropriate with the current data to suggest that CAS is superior to CEA. It is, however, quite readily demonstrable that CAS, a non-invasive procedure, is an attractive alternative to CEA in difficult surgical patients.

In order for valid comparisons of any therapeutic alternatives to be made, a sufficiently large population of patients must be randomized to minimize bias. An alternative to randomization is to adjust or compensate for differences between the groups. We have learned from the surgical RCT's that we can expect different outcomes based upon the symptom status of the patients. When non-randomized population data is examined, one must

remember the very strong selection bias for enrollment of the elderly and those patients with severe medical comorbidities in CAS protocols with independent neurological assessment. This is a completely different population from those low risk asymptomatic patients who undergo routine CEA without post procedure neurological assessment. It is not appropriate to compare populations of high surgical risk patients with those of low risk patients with disparate outcome assessments and expectations<sup>24</sup>.

The draft assessment's assertion in the second paragraph of page 6 of the CTAF that "The indications for carotid or cerebral angioplasty have varied in published reports, is detailed below. Particular patient subgroups for which angioplasty/stenting might be particularly advantageous have not yet been fully defined, although it has been suggested that patients at high risk for surgical complications represent one such subgroup" fails to recognize the obvious advantages and patient benefits of CAS as an alternative to CEA in patients at increased risk of surgical complications. Clearly, this high surgical risk group of patients has an excellent dataset supporting CAS as an effective alternative therapy compared to low, standard risk CEA patients.

**We concur that TA Criterion 2 is met for high surgical risk patients.**

**TA Criterion 3: The technology must improve the net health outcomes.**

It is a serious error to not separate the data into high surgical risk and usual surgical risk cohorts. They cannot be compared given the high event rates caused by the medical comorbidities (heart and lung disease) in the CAS group. Also the statement made by the reviewer on page 6, "There is only one small randomized trial comparing stent placement with medical management" refers exclusively to vertebral artery stent placement, not carotid stent placement and is not appropriate to consider in this discussion. High surgical risk patients treated with CAS have been proven to have "non-inferior" outcomes compared to CEA in a RCT (SAPPHIRE) published in a peer reviewed journal that now has 3 year follow up supporting the long-term benefit of CAS<sup>18 25</sup>. This data was presented to the FDA to support the first CAS system approval.<sup>18</sup> Three year outcomes have confirmed the durable and beneficial results obtained in the only randomized controlled trial in this high risk subset of patients.<sup>25</sup>

On page 15 of the CTAF, the last paragraph contains inappropriate projections, given the small sample size regarding CAS vs. CEA outcomes. The SAPPHIRE randomized trial showed no difference between CAS and CEA, but there was a "trend" toward CAS benefit. Clearly long-term follow-up is important and more is needed, but the evidence suggests that CAS does prevent further strokes as well as CEA out to 3 years.

On page 19 of the CTAF, the finding of increased severity of stenosis of CAS on follow-up is likely to an error in ultrasound velocity assessment<sup>26</sup>. Following CAS, carotid velocities rise due to loss of vessel compliance and have been shown to over-estimate the stenosis. Also the reviewer failed to note that despite the suggestion that "restenosis" was more common for CAS in SPACE at 2 years, only < 1% (n = 2) of the patients had symptoms related to CAS restenosis. The SAPPHIRE RCT actually demonstrated a lower rate of repeat revascularization for CAS (0.6%) compared to CEA (4.3%, P = 0.04)<sup>18</sup>.

Additional supporting peer-reviewed and published evidence include a meta analysis<sup>27</sup>, multiple pre-market<sup>17, 19-21, 23, 28-30</sup> and post-market<sup>22, 31-33</sup> FDA mandated investigations. Additionally, a multi-specialty endorsed professional Societal document is consistent with the randomized controlled trial and has supported the benefit of CAS in high surgical risk (anatomic and comorbid features) symptomatic (>50% stenosis) and asymptomatic (>80% stenosis) patients.<sup>34</sup> These studies support accepting CAS according to the FDA label indications, i.e. high surgical risk (both anatomic and comorbid features) patients, who have symptomatic  $\geq 50\%$  stenotic lesions or asymptomatic  $\geq 80\%$  stenotic lesions as an alternative to CEA. While there is evidence at this time to support

CAS in subgroups (SPACE) as an alternative to CEA in average or low surgical risk patients with or without symptoms, more data is needed.

**Clearly, TA Criterion 3 is met for the FDA label indications for CAS.**

**TA Criterion 4: The technology must be as beneficial as any established alternatives.**

Once again, for the FDA label indications for CAS (high surgical risk with  $\geq 50\%$  symptomatic lesions and  $\geq 80\%$  asymptomatic lesions), the SAPPHIRE trial and thousands of registry patients have clearly and unequivocally demonstrated non-inferiority for CAS with CEA. Multiple registry trials have been conducted including the Boston Scientific EPI: A Carotid Stenting Trial for High-Risk Surgical Patients (BEACH) Trial. BEACH enrolled 480 pivotal patients who were candidates for carotid revascularization but were at high surgical risk for complications due to pre-specified anatomic criteria and/or medical comorbidities. The primary endpoint (all stroke, death, or Q-wave myocardial infarction [MI] through 30 days; non-Q-wave MI through 24 hours; and ipsilateral stroke or neurologic death through 1 year), was compared to a proportionally weighted objective performance criterion (OPC) of 12.6% for published surgical endarterectomy results in similar patients, plus a pre-specified non-inferiority margin of 4%. Among pivotal patients, 41.2% were at high surgical risk due to comorbid risk factors, and 58.8% due to anatomic risk factors; 76.7% were asymptomatic with flow-limiting carotid stenosis  $>80\%$ . At 1 year, the composite primary endpoint occurred in 8.9% (40/447), with a repeat revascularization rate of 4.7%. With an upper 95% confidence limit of 11.5% for the primary composite endpoint, the BEACH trial results met the pre-specified criteria for non-inferiority relative to the OPC non-inferiority margin for historical surgical CEA outcomes in similar patients ( $p < 0.0001$  for non-inferiority).

The BEACH study's two-year results demonstrated that the ipsilateral stroke rate steadily declined from 3.1 percent from 0-30 days, to 2.3 percent from 31 days to one year, to 0.9 percent between one and two years. The BEACH study also demonstrated declining death rates from 7.5 percent through one year to 6.1 percent between one and two years. The progressive reduction in carotid duplex ultrasound peak systolic velocity from 346 cm/sec before the stent procedure to 130 cm/sec two years following the stent procedure suggests no progressive restenosis (re-blockage) from 6 months to 2 years.

**TA Criterion 4, that CAS must be as beneficial as any established alternatives (CEA) is easily met with registry and RCT data in surgical high risk patients.**

**TA Criterion 5: The improvement must be attainable outside the investigational setting.**

Over the past year, there have been three large peer-reviewed publications regarding CAS in high surgical risk post-market surveillance trials reporting on more than 8,000 patients treated outside the clinical investigational setting. The Stenting and Angioplasty with Protection of Patients with High Risk for Endarterectomy World-Wide (SAPPHIRE WW) post-market approval registry trial evaluated 30-day outcomes after CAS in high surgical risk patients with CAS operators of widely varying experience.<sup>13</sup> Independent neurologic assessment was employed for outcomes assessment. The investigators reported 30-day safety and efficacy outcomes in 2,001 symptomatic and asymptomatic high surgical risk patients (anatomic = 716, comorbid = 918, and both = 327) treated by carotid stent operators with varying clinical experience. Approximately 72% were asymptomatic and 28% were symptomatic. The criteria for anatomic or comorbid surgical risk features were based on the FDA labeling for the devices. The primary endpoint of composite adverse outcomes included combined stroke (based

on independent neurologic assessment using NIHSS and Rankin scales), death, and myocardial infarction. The overall, independently adjudicated, 30-day stroke and death rate for CAS in 2,001 high surgical risk patients was 4.0%.

In the asymptomatic SAPHIRE World-Wide patients, the adverse outcome rate was 1.8% in the anatomic subgroup and 3.0% in the comorbid subgroup, within the 3% limit required by the AHA Expert Consensus group. For symptomatic patients, the overall adverse event rate was again lower than the 6% rate described by the AHA consensus document for the anatomic subgroup at 4.5% and rose to 8.3% in the comorbid high-risk group. Importantly, this study involved nearly 350 sites and operators with a wide variety of experience, suggesting that the outcomes from prior pre-market approval (PMA) trials are generalizable<sup>13</sup>.

Two other large post-market registry trials, EXACT and CAPTURE-2, reported on more than 6,000 high surgical risk patients treated by CAS operators with varying levels of experience in large prospective, multi-center, registries (EXACT [n = 2,145]; CAPTURE-2 [n = 4,175]).<sup>14</sup> Both trials included independent neurologic assessment of outcomes, to reinforce the rigor for ascertaining adverse events. The overall incidence of 30-day stroke and death for 2,145 EXACT patients was 4.1% and for the 4,175 CAPTURE-2 patients was only 3.4%. Importantly, for patients that would have been comparable to patients included in the 2006 AHA published guidelines (<80 years)<sup>16</sup>, the CAS results met the threshold recommendations for 30-day stroke and death rate for symptomatic patients ( $\geq 50\%$  stenosis) at 5.3% (Benchmark for CEA  $\leq 6\%$ ) and for asymptomatic patients ( $\geq 80\%$  stenosis) at 2.9% (Benchmark for CEA  $\leq 3\%$ ).<sup>14</sup>

**TA 5 is obviously achieved for high surgical risk patients.**

## Summary

With the focus on high surgical risk patients, all five of the specific TA criteria are met for CAS. The crucial question is not whether CAS is a superior carotid revascularization technique to CEA, but rather, in which patient population is CAS as good and safe as CEA. There is now overwhelming evidence supporting CAS in selected patients as a valid alternative to CEA in patients with high risk anatomic features and medical comorbidities. This is consistent with FDA labeling. The recent peer-reviewed publications of more than 8,000 high surgical risk patients<sup>13 14</sup> meeting and exceeding published carotid revascularization benchmarks<sup>16</sup> for 30 day stroke and death risks makes an irrefutable argument for accepting CAS indications that are broadly consistent with the FDA labeled indications for the devices.

We would also like to express appreciation to the lead author of this response Chris White, M.D. FACC, FSCAI and the following physicians who assisted in this effort, Michael Jaff, D.O, FACC and Bonnie Weiner, M.D. FACC, FSCAI. We greatly appreciate their efforts to develop this response in less than a week. We also note that all three of our organizations support use of carotid registries such as CARE to further assess efficacy and safety of CAS in our nation for other subgroups of patients and also to better understand safety and efficacy and post market surveillance of the varied CAS devices now being used and also under present development. (See: <http://www.ncdr.com/webncdr/CarotidStent/default.aspx>) If you would like to communicate with any of our leaders regarding this document, please contact, Dawn Hopkins at SCAI ([dhopkins@scai.org](mailto:dhopkins@scai.org) or 202.741.9854), Denise Mueller at SVM ([dmueller@vascularmed.org](mailto:dmueller@vascularmed.org) or 847.480.2961) or Henry McCants at ACC ([hmccants@acc.org](mailto:hmccants@acc.org) 202.375-6642).

CTAF – Carotid Stenting

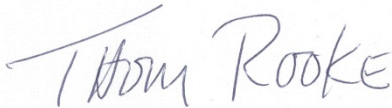
June 13, 2009

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Sincerely,

A handwritten signature in black ink, appearing to read "Steven R. Bailey". The signature is fluid and cursive, with a prominent initial "S" and a trailing flourish.

Steven R. Bailey, M.D., FSCAI,  
President  
Society for Cardiovascular Angiography and Interventions

A handwritten signature in black ink, appearing to read "Thom W. Rooke". The signature is written in a clear, slightly cursive style.

Thom W. Rooke, M.D.  
President  
Society for Vascular Medicine

A handwritten signature in black ink, appearing to read "Alfred A. Bove". The signature is highly stylized and cursive, with a large initial "A" and a long, sweeping tail.

Alfred A. Bove, M.D. FACC  
President  
American College of Cardiology

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