



February 28, 2007

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Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

RE: Proposed Decision for Carotid Artery Stenting CAG-00085R3

Dear Dr. Phurrough;

The Society for Vascular Surgery represents over 2,300 physicians in the United States. SVS offers the following comments regarding Proposed Decision of the Medicare National Coverage Policy for percutaneous transluminal angioplasty of the carotid artery with stenting, CAG-00085R3. SVS appreciates the thorough and ongoing effort expended by the CAG to allow responsible introduction of this exciting technology.

As CMS works to provide an evidence-based coverage policy for CAS, consideration of the following new studies is important. These were not included in the CMS CAS bibliography published in February 2007.¹

- Debing and Van den Brande undertook a prospective analysis of 1002 CEAs in Belgium to assess the 30-day complication rate in relation to the patients' cardiovascular risk factors. The 30-day combined CEA minor and major stroke and death rate was 2.7%. While diabetes was an independent risk factor, the simultaneous presence of three cardiovascular risk factors was required to significantly raise the stroke/death rate. With 3 risk factors, stroke/death rate was 5.3%, $p=0.012$, $OR=3.11$.²
- Westvik et al used a statewide database in Connecticut to examine all symptomatic and asymptomatic non-federal CEAs in that state between 1991 and 2002. Complications for 14,288 CEAs included 0.5% mortality and 1.3% stroke.³
- Kragsterman et al reviewed CEA outcomes on all asymptomatic patients who underwent CEA in Sweden, 1994 to 2003. Data were culled from the Swedish Vascular Registry, and four validation methods were undertaken to assure accuracy. Of 6182 total CEAs during the interval, 671 patients were asymptomatic. Stroke or death in asymptomatic

patients over the entire period (2.1%) improved to 0.9% (3/341) from 1999 to 2003 (P=0.026).⁴

- Cao et al performed a retrospectively matched case-control study of 301 CAS with EP subjects to an equal number of CEA patients. Matching was by gender, age, neurologic symptoms and coronary disease. The 30-day risk of stroke was higher for CAS patients (7.9% vs 2.3%; OR 5.2; 95% CI 1.7 to 18; P=0.001), and the disabling stroke/death rate was 2.6% for CAS and 1.3% for CEA (OR 2; 95% CI, 0.54 to 9.35; P=0.4).⁵
- Mureebe et al examined CAS and CEA hospital inpatient discharge data from California and New York for the year 2005. Comorbidities associated with, or those possibly affecting, the outcome of carotid intervention were analyzed. The population included 14,785 CEA and 2,554 CAS. Mortality for patients undergoing CAS was double that of CEA (CAS=1.41%, CEA=0.64%, p<0.0001). Post-procedural stroke for CAS was double that for CEA (CAS=2.19%, CEA=1.24%, p=0.002). When the analysis was focused on patients who met high risk criteria (n=7,996), multivariate logistic regression identified CAS as a predictor of peri-procedural stroke (odds ratio 1.82, 95% confidence interval: 1.262-2.625) and mortality (OR 2.604, 95% CI 1.583-4.284).⁶
- McPhee et al used a combination of ICD9 codes for carotid artery stenosis, CEA and CAS to identify and examine patients who underwent carotid revascularization in the National Inpatient Sample. The primary outcome measure was in-hospital mortality. By logistic regression analysis of 217,468 discharges during 2003-2004, controlling for diagnosis type and medical comorbidities, CAS was independently predictive of increased in-hospital mortality as compared to CEA (OR 2.66; 95% CI 1.63-4.34). Other significant factors included the diagnosis of stroke and the presence of congestive heart failure or renal failure but gender or hospital type (teaching vs. non) did not affect mortality rates.⁷

I. SVS strongly supports “the Opinion of a Surgeon”

The Proposed Decision states “we are proposing that we modify the standard to require that the patient’s high risk status be determined by a surgeon credentialed to perform CEA”. SVS strongly supports this proposed requirement. If CMS expands the CAS coverage policy to include asymptomatic high-surgical-risk patients, the credentialed CEA surgeon will provide clinical balance for thousands of enthusiastic CAS providers, some with little or no experience caring for carotid disease patients, many of whom are likely to forge extremely liberal interpretations of high surgical risk. This is especially important as an increasing body of literature demonstrates that several of the so-called “physiologic” cardiopulmonary high-risk indicators used in CAS investigations and registries do not have a negative impact on CEA morbidity or mortality. Therefore, SVS strongly supports the CMS proposal to mandate a pre-CAS surgical risk assessment by a CEA expert.

Based on two separate lines of evidence, SVS believes that experienced CEA surgeons can identify patients at high risk for surgery more accurately than any list of individual co-morbid

factors. First, large population studies cited below indicate that individual “physiologic” risk factors do not appear to increase the morbidity or mortality of CEA. Second, as population based studies document increasingly excellent CEA outcomes, one conclusion is that surgeons are not only becoming more expert at the technical aspects of CEA, but they have become experts at choosing appropriate CEA patients. If surgeons can identify those who will undergo CEA safely, the converse must also be true; these surgeons are experts at identifying patients who are truly at high-risk for surgery. If individual cardiopulmonary risk factors do not increase the risk of CEA, the experienced CEA surgeon’s clinical judgment may help the most in making this distinction. Finally, the surgeon may also help answer the question “Is the high surgical risk patient best suited for CAS or for intensive medical therapy?”

As CMS attempts to objectify definitions of the high-surgical risk patient, consideration of the following data is important. These large studies failed to identify single cardiopulmonary or cardiovascular risk factors as markers for increase CEA complication rates.

- As detailed above, Debing and Van den Brande studied 1002 CEAs in Belgium to assess the 30-day complication rate in relation to the patients’ cardiovascular risk factors. 30-day combined CEA minor and major stroke and death rate was 2.7%. While diabetes was an independent risk factor, the simultaneous presence of three cardiovascular risk factors was required to significantly raise the stroke/death rate. With 3 risk factors, stroke/death rate was 5.3%, $p=0.012$, $OR=3.11$.²
- Stoner et al reviewed NSQIP data for all patients undergoing primary isolated CEA at 123 VA and 14 private sector hospitals from 2000-2003. Study end-points were any stroke, death or cardiac event. NSQIP is an extremely accurate database. All medical records are reviewed individually by highly trained nurses who are completely independent from any potential clinical influence. Outcome analysis of 13,622 mostly male patients demonstrated a composite stroke, death, or cardiac event rate of 4.0% and a stroke/death rate of 3.4%. Cardiopulmonary co-morbid features did not affect the composite outcome in this model.⁸

The following population based studies indicate that surgeons have become very competent at identifying (and avoiding) high-surgical risk patients, and therefore are well suited to identify appropriate CAS (or medical treatment) candidates.

- As detailed above, Westvik et al examined all symptomatic and asymptomatic non-federal CEAs performed in Connecticut between 1991 and 2002. Complications for 14,288 CEAs included 0.5% mortality and 1.3% stroke.³
- As detailed above, Kragsterman et al reviewed CEA outcomes on all asymptomatic patients who underwent CEA in Sweden, 1994 to 2003. Four validation methods were used to assure accuracy. Of 671 asymptomatic patients, stroke or death rate over the entire period (2.1%) improved to 0.9% (3/341) from 1999 to 2003 ($P=0.026$).⁴
- Matsen performed an administrative database review in Maryland and California, using several validation methods, to identify hospital complication rate. In California from

1999 to 2003, 232 in-hospital strokes occurred during 51,331 CEAs (0.45%). Annual death rate over this interval ranged from 0.78-0.91%. This represents a maximum of 1.36% in-hospital stroke or death rate for a symptomatic/asymptomatic blended population. In Maryland, the in-hospital stroke rate was 0.29-0.65% per year from 1996-2003, with annual death rates from 0.33-0.58%. Thus, for asymptomatic plus symptomatic patients the maximum Maryland in-hospital stroke or death rate was 1.23%.⁹

- Finally, in selected patients, CEA risk may be largely a function of concern for a general anesthetic. The role of regional (i.e. local) anesthesia has recently been proven an effective strategy to lower overall CEA risk.^{8,10}

Additional new information derives from a recent SVS survey on practice patterns, in which 78% of responding vascular surgery practices offer carotid stenting. This information serves to refute the argument that surgeons will attempt to protect surgical “turf”. SVS would be pleased to provide the details of this survey to CMS.

It may not be widely known, and is therefore important to point out, that the typical vascular surgeon provides medical treatment and subsequently follows many patients with moderate and severe carotid stenosis in whom the lack of symptoms and/or presence of comorbidities lead the seasoned practitioner to recommend against CAS or CEA. In conclusion, vascular surgeons are the only specialists involved in treatment of carotid disease who routinely provide all three carotid disease treatment modalities, including best medical therapy, CEA, and CAS. We believe, for these reasons, the CEA surgeon can provide the single most accurate and unbiased determination of the patient who will be at high risk for surgery.

II. SVS supports restricting coverage to exclude those ≥ 80 years of old

Rescinding coverage for octogenarians is the only responsible choice based on the available data. Through investigational protocols we must seek the means and methods to safely provide CAS for our very senior citizens, but until we do so, CAS in octogenarians should not be a routinely covered service.

III. SVS does not support expansion of coverage to asymptomatic patients with “physiologic” high-risk comorbidities.

CMS is proposing a significant expansion of CAS coverage to include asymptomatic patients at a point in time when (1) the newest Level 1 studies fail to show non-inferiority of CAS compared to CEA, and (2) the peri-procedural stroke/death rate from CAS appears to have reached a hopefully-temporary plateau at a level almost twice the 3% upper limit established by the AHA for treatment of asymptomatic carotid lesions. Simultaneously, contemporary population based studies of CEA demonstrate peri-procedural stroke or death rates $< 3\%$ for asymptomatic patients (0.9% from Kragsterman et al; 2.28% from Halm et al).^{4,10}

In its September 2006 comment on CAS coverage, SVS recommended expansion into the asymptomatic patient cohort based on surgical data demonstrating above-baseline complication rates for CEA in patients with anatomic high-surgical risk factors. These include patients with:

- previous CEA with recurrent stenosis
- prior radiation therapy to neck or previous ablative neck surgery (e.g. radical neck dissection)
- surgically inaccessible cervical lesion, above C2
- CCA lesion below the clavicle
- contralateral vocal cord palsy
- presence of tracheostomy stoma
- contralateral internal carotid occlusion

SVS still believes and recommends that this is the only group of asymptomatic patients in whom CAS should be covered routinely. Reasons not to expand beyond this include elemental consideration that asymptomatic carotid stenosis in patients with truly limiting or manifest systemic comorbidities (e.g. malignancy with poor prognosis, advanced LV dysfunction such as LVEF <25%, advanced chronic kidney disease, or oxygen-dependent COPD) should be managed with optimal medical therapies and not carotid intervention of any kind. Such patients have limited life expectancies and accordingly will not benefit from treatment for asymptomatic carotid stenosis.

In addition, clinical logic defies treatment of carotid disease prior to treatment for coronary disease in patients with unstable angina. These patients need to undergo coronary evaluation and treatment before rushing to CAS. It is unreasonable to think that a person with unstable angina but no neurological symptoms should consider CAS prior to, or instead of, coronary artery treatment. These patients should undergo coronary evaluation with recognition that they harbor an asymptomatic carotid stenosis. If coronary bypass surgery (CABG) is indicated, a concomitant and effective management strategy is combined CEA and CABG, rather than CAS and CABG. While the logic may not be immediately apparent, it becomes so when one considers the negative impact of CAS-required anticoagulation (e.g. Plavix) on the outcome of CABG. Plavix substantially increases the incidence of post-CABG hemorrhage. For all the above-noted reasons, SVS recommends unstable angina be removed from the list of physiologic high-risk comorbidities that would allow for CAS coverage.

Note that this strategy of combined CEA/CABG is also germane to the high-risk criterion “in need of open heart surgery”. The literature supports the safety/efficacy profile of a combined CEA/CABG surgical approach.¹¹ Additionally, in large database studies that provide propensity scoring, case controlled methodology explains the nature of risks incurred with intervention in such patients.¹²

SVS recommends that the category “Other conditions that were used to determine high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.” be removed from the list of approved indications because this ill-defined marker opens the floodgate for indiscriminate application of CAS. If CMS hopes to provide reasoned diffusion of CAS, “Other conditions...” should be eliminated.

SVS is also very concerned that expanded coverage based on insufficient data will have the unintended effect of eliminating ability to recruit for the randomized controlled trials that hold great promise in helping us determine the best application of CAS. Expansion of CAS coverage to include physiologic high-risk asymptomatic patients will make it nearly impossible to complete recruitment for crucially important RCTs such as CREST and ACT1. Many questions about CAS remain to be answered. CMS and other governmental agencies should support to the maximum possible extent, RCTs and other prospective objective scientific comparisons of CAS, CEA and medical therapy to help determine the optimal means to reduce stroke in specific subsets of symptomatic and asymptomatic Medicare beneficiaries.

IV. SVS agrees that CAS should NOT be expanded to cover symptomatic patients with 50-70% angiographic stenosis.

According to NASCET results for symptomatic patients with 50-70% stenosis published in 1998, the natural history risk for stroke with medical therapy is 22% at 5 years, or approximately 4.4% per year.¹³ These patients have a less foreboding natural history risk than symptomatic patients with 70-99% stenosis. In ARCHEr, the 30-day stroke, death and MI rate was 13.0% for symptomatic patients. This means that within 30-days of treatment, CAS results in more than half the morbidity and mortality of the entire 5-year experience of NASCET patients. Expansion to the 50-70% high-risk symptomatic group cannot be justified without convincing RCT data.

V. SVS opposes exclusion of coverage for all CAS without Embolic Protection. These should be covered under appropriately limited circumstances.

In the Proposed Decision, CMS reaffirms that CAS will be covered only when performed with an embolic protection device, denying the recommendation of SVS and other specialty societies for coverage of CAS without EP under extenuating clinical circumstances. Specifically, SVS recommends coverage for CAS without EP when: 1) the operator documents that, due to patient-specific anatomic findings, the risks of embolic protection exceed potential benefits, or 2) the operator documents reasonable attempts to deploy embolic protection and sites the technical reasons why this was not possible.

SVS acknowledges the fact that the data supporting coverage derives from studies of CAS with embolic protection, but CAS experts agree there are rare exceptions wherein CAS is undertaken most appropriately without EP. In these situations, the provider and the facility should be reimbursed.

The current policy forces the CAS provider to make a decision that pits payment directly against best medical care. For example, a 70 year-old patient with class IV congestive heart failure suffers a minor stroke and is found to have an 80% carotid stenosis. The CAS operator performs a diagnostic arteriogram confirming the severely stenotic lesion but additionally identified is an extremely tortuous internal carotid artery. Reasonable attempts to pass the Embolic Protection device through the tortuosity fail. The CAS operator then faces a dilemma. He/she can 1) abort the procedure thereby subjecting pt to natural history risk for stroke (~26% over 2 years), 2)

attempt to force the embolic protection device into place risking distal artery injury, or 3) perform CAS without EP, foregoing payment to provider and facility. It is unreasonable that the CAS provider should forego payment for making the best patient care decision.

If CMS is concerned that providers will disregard the scientific literature, avoiding EP use during routine practice, it seems this could be effectively dealt with during the facility recertification process. Facilities could be recertified only if their providers maintain a high usage of EP, perhaps >95%. Providers could additionally be instructed to use coding modifiers demonstrating the unusual nature of the procedure. For instance, the CPT code for CAS without EP (37216) could be submitted with the “-22” unusual procedure modifier, and payment could be conferred only if circumstances were documented in the procedure dictation. In fact, CAS with vs. without EP could even be made into a pay-for-performance measure, requiring that at least 95% of CAS be performed with EP in order to meet quality performance guidelines.

In summary, SVS believes that clinical situations exist wherein CAS without EP provides the best clinical treatment for the patient. When this occurs, the CAS provider and facility should not be financially penalized for using good clinical judgment.

VI. SVS supports physician-based CAS facility recertification programs, but we do not support CMS exclusive delegation of this responsibility to SCAI CAP.

SVS appreciates the additional details provided by CMS regarding facility recertification, an event that lies in the immediate future for many facilities. SVS believes that recertification is an activity best assumed by specialty-neutral accrediting agencies, similar to those very successful efforts for noninvasive vascular laboratories, echocardiography facilities and nuclear medicine diagnostic labs (e.g. ICAVL, ICAEL, ICANL). These examples have all stemmed from truly “intersocietal” efforts rather than single-specialty programs.

SVS respects the initiative taken by SCAI in development of their Carotid Accreditation Program (SCAI-CAP), but we are concerned about its specialty-specific roots and cardiac cath-lab focus. Regarding the SCAI-CAP documents,^{14,15} SVS finds the described level of our society’s involvement to be overstated. SVS has had very limited discussions with SCAI regarding SCAI CAP, and SVS leadership had not seen the SCAI-CAP accreditation program overview or the SCAI CAP program application prior to publication of the CMS Proposed Coverage rule on February 1, 2007.

SVS is committed to participation in a specialty-neutral initiative that would assume the CAS facility recertification role. This specialty-neutral entity could be established in parallel with SCAI-CAP, or perhaps the SCAI-CAP program could be folded into a more broad-based intersocietal effort. The biggest problem we see is continuation of the CMS program because it is difficult to envision many facilities choosing a rigorous and expensive non-CMS certification program when a less rigorous and cost-free direct CMS certification remains available. In order for independent certification / recertification programs to succeed, CMS will need to discontinue its direct certifying mechanism and endorse the independent program(s).

VII. SVS appreciates CMS' recognition of the SVS Vascular Registry

SVS put forth a major effort to provide the Vascular Registry. We were pleased to see our efforts acknowledged in the CMS document, but more importantly, we view the Registry as a means to help solve some of the perplexing CAS problems. We hope to continue collaborative efforts with CMS to reap benefits for our cerebrovascular disease patients.

Conclusion

SVS thanks CMS CAG for their continued efforts to provide appropriate coverage for CAS. We are committed to the advancement of all forms of carotid therapy with the overall goal of reducing morbidity and mortality from stroke. We are available at any time for telephone or in-person discussions regarding our comments.

K. Craig Kent, M.D.
President
and the Executive Council of
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