



The Society for Cardiovascular Angiography and Interventions

SCAI President's Page

“The Year of the Carotid”: What I've Learned (So Far...)

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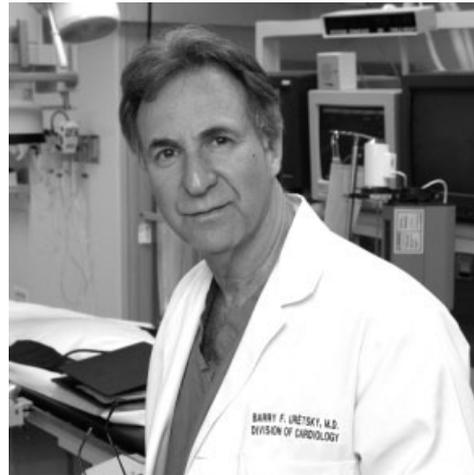
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The current year was described by our outgoing president, Dr. Michael Cowley, as the “Year of the Carotid” in his remarks at this May’s SCAI Annual Scientific Sessions. A few months earlier, one member, in mock frustration, asked me if the “C” in “SCAI” stood for “Carotid.” In reality, it was a year where the pace of developments in carotid intervention quickened dramatically, with your Society responding vigorously on many fronts.

From May 2004 to May 2005, as President-Elect, I had the privilege of serving on the Society’s Executive Committee as a member of the leadership and a tutored pupil for the top volunteer job. As a result, I had a unique vantage point to listen and learn about carotid artery disease, carotid stenting (CAS), and how we as interventional cardiovascular specialists may be able to help patients with this problem. The good news: as the discussion below demonstrates, many dedicated members of the SCAI leadership have been working intensively on your behalf on many fronts. Their hard work has led to real progress.

Let me share with you the most important issues from my perspective and urge you to let me know what YOU think.

The Importance of Treatment

The majority of those reading this page have been told by some of their patients that they’d rather die than sustain a major stroke. As doctors and cardiologists, we know the devastating effects of stroke and the importance of diagnosing and treating carotid artery stenosis. The need to prevent a stroke has motivated many of us to push for the promulgation of CAS as an alternative to carotid endarterectomy (CES). While CES is a proven and effective treatment, it has its drawbacks and limitations. Development of CAS with distal protection has expanded the potential for safely treating carotid stenosis and preventing stroke. This new addition to our therapeutic armamentarium is unarguably a major advance in our ability to care for our patients.

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The Cardiologist as a Cardiovascular Specialist

In 2003, the Society changed the “C” in its name from “Cardiac” to “Cardiovascular,” recognizing the importance of our specialty in intervening in vascular beds in addition to the coronaries. However, the curriculum in general cardiology training has lagged behind in formally endorsing this inclusion as part of the cardiologist’s corpus of knowledge. In fact, in internal medicine, there exists the anomalous situation of a vascular disease diagnostic workup being referred in most institutions to a surgeon. It is difficult to think of another comparable example in all of internal medicine.

Additionally, as Dr. Gary Roubin stated in the Hildner Lecture at this year’s SCAI national meeting, CAS has emphasized the artificiality of the barriers that exist between the interventional cardiologist, the interventional radiologist, and the vascular surgeon while also emphasizing that the “cardiologist” is really shorthand for “cardiovascular specialist.” To foster that important mindset, your Society intends to propose formal training and education in pathophysiology, diagnosis, and management of vascular disease as part of every trainee’s program. We are currently working with other major cardiology organizations in this regard.

The Need for Guidelines

In a scant four months (quite possible a guidelines record!), SCAI, under the leadership of Drs. Ken Rosenfield and Mike Cowley, in cooperation with the Society for Vascular Surgery and the Society for Vascular Medicine and Biology, prepared a comprehensive clinical competency statement for the performance of carotid stenting (the document was subsequently endorsed by the American College of Cardiology). This was a superb example of how different medical disciplines whose interests overlap in a common area can work together effectively toward the promotion of excellence in clinical care.

The speed at which the guidelines were produced mirrored the concern that once the federal Centers for Medicare and Medicaid Services (CMS) approved payment for CAS, dissemination of this procedure might be faster than would be the supply of properly trained physicians to perform the procedure safely. The multi-specialty society clinical competency statement is an attempt to delineate rigorous yet reasonable standards to safely perform CAS by a capable operator [1].

A key focus: the competency statement does not recommend limiting the performance of CAS to any specialty. Rather, it emphasizes the cognitive and tech-

nical skills the operator needs as well as resources and logistics required at the performing institution. No one would say the competency statement is “perfect” (and in fact it is likely to be revised over time as experience warrants), but it is an honest, inclusive attempt to increase CAS utilization safely. Cardiovascular interventionists believe they are uniquely poised to be the primary CAS practitioners because of their technical expertise in percutaneous intervention and stenting, their experience in hemodynamic monitoring, and the historical precedent from the pioneering efforts of interventional cardiologists such as Drs. Roubin, Iyer, and Yadav. On the other hand, other specialists, including interventional radiologists, vascular surgeons, and neurologists who have had adequate interventional training and experience should be able to perform this important procedure. In fact, a combined cooperative effort is, in theory, ideal. However, as Dr. Chris White recently stated: “Cooperation among disciplines is very important, but it is our obligation to our patients as interventional cardiologists to perform the procedure.”

The Importance of Institutional Approval

The Society and other organizations have emphasized the importance of the competent operator performing the procedure in the appropriate environment which includes adequate imaging equipment, hemodynamic monitoring, neurological evaluation and follow-up, and a quality assurance program. CMS has stated that it will approve payment to qualified institutions. Who will judge the adequacy of the institutional system? Who will determine what “qualified” means? CMS has stated that it will accept the review of multiple agencies.

In response, SCAI is developing a process to review institutional adequacy. SCAI approval should be considered “site qualification” [adequacy of certain clearly defined parameters] as opposed to “accreditation” [approval of a facility to perform CAS] or “credentialing” [approval of an individual to perform CAS at the institution].

The Importance of Education

The Society has recognized the importance of physician education as a crucial aspect in safely promulgating CAS. The first SCAI course was organized and held within four months following conception under the direction of Drs. Chris Cates and Mike Cowley and an extremely dedicated steering committee composed of Drs. Ted Feldman, Nick Hopkins, Michael Jaff, Ken Rosenfield, Gary Roubin, and Chris White. Despite the almost “stealth” aspect of minimal adver-

tising, the three-day course held this April in Atlanta, GA, attracted over 200 registrants.

The course is the first of a three-part integrated curriculum in CAS, all driven by the clinical competency guideline described above. Parts two and three are, respectively, an online self-assessment module (available at www.scai.org by the time this column reaches you) and simulation exercises at designated centers throughout the country. The Society endorses the concept of simulation as a potentially safer method to train new operators. The Society has not endorsed any particular vendor's product including those used in this course but does believe that simulation, even if imperfect, represents a valuable practice environment for the new operator.

In sum, there is almost a "cottage industry" in carotid stent courses at present. To the extent that such courses provide the cognitive aspect to potential operators, they are of importance to the safe introduction of this technique to a wide audience.

Payment: A Crucial Factor

A key factor in delaying promulgation of CAS is lack of proper reimbursement to the physician and hospital. The Society was one of a number of organizations that encouraged CMS to provide broad CAS coverage. The recent CMS pronouncement to limit payment to symptomatic patients will continue to withhold this procedure from the majority of patients who might benefit since 80% of patients with severe carotid stenosis are asymptomatic. CMS has correctly written that the scientific data on CAS in asymptomatic patients are limited. CMS has used these limited data as a justification to not approve payment for such patients.

As a scientist, I have to admit that it is possible that in the asymptomatic group, CAS may be more risky than CES, but in my heart I know that it isn't true. Further, I suspect that CMS may feel that denying coverage for the asymptomatic group may be cost-saving

insofar as there may be less overall carotid interventions (CAS+CES) in this scenario, as some physicians may treat their patients medically rather than with CES (although they might have recommended CAS if available). As physicians we must always consider the patient's welfare first and are thus conflicted about the current situation. Personally, I will continue to perform CAS on asymptomatic patients with severe lesions as it is, in my opinion, the right thing to do and will ultimately be recognized as such, hopefully in the near future.

The Real Bottom Line

The present data are strong enough to allow CAS to be an alternative to CES in symptomatic patients. The data are not as strong in asymptomatic patients. It seems highly unlikely, however, that CAS is less safe than CES in this setting. Thus, since CES has shown the ability to prevent stroke in this patient subgroup, particularly with high-grade lesions of 80%, it is very likely that CAS will be as effective as CES, and probably safer. Therefore, it seems reasonable to utilize CAS presently when possible in this patient subgroup and continue to encourage CMS and other insurers to authorize payment. We must work with our hospitals and do what is right for our patients.

I would like to hear from you. You can contact me at president@scai.org

REFERENCE

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