

Barriers to Carotid Artery Stenting Dissemination

A look at the factors contributing to the slower-than-anticipated growth of carotid artery stenting in the US.

BY GARY S. ROUBIN, MD, PhD

It has been 3 years since the first carotid artery stenting (CAS) system was approved for commercial sale in the US. In challenging the proven gold standard of carotid endarterectomy (CEA), CAS has faced a difficult path to acceptance from the beginning, but after its FDA approval, many in the industry believed that the procedure would quickly become the standard of care in most patients. However, after enduring the scrutiny of the original clinical trials, a thorough review by the FDA, and several years of availability, CAS still faces a number of significant barriers to widespread dissemination, including the Centers for Medicare & Medicaid Services (CMS) reimbursement, proper patient selection, and optimal training for operators.

CMS REIMBURSEMENT

Reimbursement for a new procedure from CMS requires the demonstration of clinical effectiveness and value in terms of efficiency, cost effectiveness, and resource utility action. The prime question is why, after more than a decade of experience with carotid stenting, has this not been achieved? The first reason, of course, is that this method of revascularization required significant technique and device development before achieving acceptable results. This can only come about through clinical experience and device development that takes considerable time. Awareness that suitably designed self-expanding stents were optimal and embolic protection was necessary occurred during the first 5 years. The optimal technical

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approach continues to evolve.

Second, carotid stenting sparked the most intense turf war that we have seen in percutaneous intervention during the last 30 years. On this 30th anniversary of the first coronary angioplasty by Andreas Grüntzig, MD, we are able to reflect on the challenges he faced from surgeons at the time over his new method of coronary revascularization.

Similar circumstances prevailed a decade ago when our group of cardiologists and neurologists from the University of Alabama at Birmingham presented the first prospective, institutional review board approved outcome analysis. Claims all around were clearly overstated. The loudly voiced assertion that stenting could never produce safe results in the complex lesion morphology at the carotid bifurcation has clearly proved to be wrong. Similarly, statements to the effect that stenting would totally replace CEA have also proved incorrect. The position of the vascular surgical community was understandable. In essence, vascular surgeons had much to lose and seemingly little or nothing to gain from supporting the

development of carotid stenting. What a difference a decade made!

The third reason—and to the surgeons' credit—has been the large amount of level-one scientific data supporting the use of CEA compared to medical therapy on the treatment of carotid bifurcation disease. It is fair to say that few new revascularization techniques have faced such resistance and challenges in the history of percutaneous intervention.

Nonetheless, there have now been tens of thousands of patients treated with stenting in the US and many more worldwide. In the US, the procedure remains in a state of confused limbo. Under the current CAS national coverage policy, large numbers of Medicare patients who might benefit from the less-invasive procedure are denied access. Privately insured patients can seek out experienced operators and benefit from the procedure and avoid the known complications associated with the neck incision required for CEA.

Rigorous rules apply to CMS reimbursement regarding lesion severity (>80% diameter stenosis), definition of high CEA risk, and symptom status. In certain states, there is mandatory reporting to CMS of 30-day outcomes.

In the meantime, CEA continues to be performed with no such restrictions or oversight. Patients, many asymptomatic, are routinely operated upon based on duplex findings, many from nonaccredited laboratories with or without confirmatory MRA or CTA assessment of lesion severity from both good and bad image centers. In our experience, these latter imaging modalities also tend to overestimate lesion severity. In our institution, fully one third of patients referred for carotid stenting are sent home on medical therapy after angiographic studies fail to demonstrate sufficient lesion severity to warrant revascularization.

This confused and frankly irrational situation exists because of the failure of interested parties—interventionists, surgeons, and neurologists—to provide any clarity to the federal agencies. There continues to be considerable debate over the need for revascularization in asymptomatic patients and where to set the bar on lesion severity. Collaboration among professional societies remains, at best, circumspect, and these organizations continue to work largely in the interest of their members.

The News Is Not All Bad

The best example of multidisciplinary collaboration is represented by the CREST study group, where neurology, vascular and neurosurgery, interventional cardiology, and neuroradiology have toiled for years to gather rigorous, prospective randomized data on stenting and CEA. With more than 2,000 patients randomized and recruitment predicted for completion in mid-2008, we can expect to

see some definitive data by late 2009. The ACT I prospective randomized trial is also recruiting well but will be unable to provide outcome data for at least another 4 years.

Accordingly, we need to move forward using the large prospective data sets available from the multicenter post-marketing registries. This real-world, community experience has provided exceptionally valuable data.

The outcomes in this large, clinically complex population that includes very elderly patients with a variety of real world comorbidities are simply stellar. Average 30-day stroke and death rates in asymptomatic patients <80 years of age are very close to the 3% guideline requirements. These data are concordant through the CAPTURE, XACT, and CREST (Lead-In) registries. The large, rigorously monitored CREST lead-in registry demonstrated remarkably low 2% stroke and death rates at 30 days in patients <70 years of age. Hundreds of operators in as many institutions contributed patients to this data set.

The rational conclusion should be that given the right operators and properly selected patients, carotid stenting is a safe, effective, and valuable procedure.

The News Is Not All Good

Certain subsets of patients did not have acceptable results. For example, the symptomatic subset in CAPTURE had a 12% 30-day stroke and death rate. Similarly, elderly patients in all registries had unacceptable outcomes. These data suggest more challenging clinical and anatomical subsets require the expertise and good clinical judgment of more experienced operators. This should not be any great surprise!

PATIENT SELECTION

One of the most significant problems we have faced in gaining CMS reimbursement has been our inability to identify and define patients who are good candidates for stenting and then focus our IDE studies, postmarket studies, and randomized studies on those patients. Because we have a well-validated surgical alternative, there is no reason to offer patients CAS unless they are good candidates. Many published studies have shown low complication rates that meet the guidelines set by the American Heart Association and the Society for Vascular Surgery. It is very clear that these operators are able to achieve excellent results by carefully selecting their patients and that they are not offering stenting to patients who have both clinical and anatomical factors that make them unsuitable candidates for the procedure. We have not done enough to disseminate this information to the wider body of interventionists. Accordingly, many of the negative outcomes we have seen have been related to poor patient selection. We should not use the

disclaimer that these are high-risk CEA patients in order to explain less-than-adequate outcomes for stenting. Good operators can carefully select patients who are at high risk for surgery but low risk for stenting and produce excellent results. All CAS procedures should be reimbursed by CMS, provided that the hospitals and operators can produce these acceptable outcomes.

We absolutely underestimated the need for careful patient selection in producing acceptable carotid stenting results. The clinical and anatomic factors that increase stroke and death rates are now becoming apparent. Subtle combinations of adverse factors such as advanced age, decreased cerebral reserve, difficult arch anatomy, vessel tortuosity, lesion calcification, disease in the common carotid segment of the bifurcation, occlusion of the external carotid, etc, all contribute to complications. Advanced cognitive and technical skills are required to select patients and negotiate these issues successfully.

TRAINING AND EVALUATION

Many vascular surgeons, interventional radiologists, and interventional cardiologists watching highly experienced operators perform these procedures assumed that they could easily translate the endovascular skills that they had learned in the iliac, femoral, aortic, and cardiac interventional work, to the carotid artery. This is not the case. When I look at outcomes in the community, from all of these groups of operators, I see results that are not acceptable. We must assume that our training efforts have been suboptimal.

The initial analyses of operator experience that were done in the postmarket studies had arbitrary and inadequate definitions of low-volume, medium-volume, and high-volume operators—that showed no difference in outcomes. The conclusion that has been drawn by some is that this indicated that operator experience is not important; this is incorrect. Frankly, these observations had more to do with the way we defined the experience of the operators.

It is difficult to determine which elements of today's training programs should be mandatory. It does depend foremost on the operator's background skills, which vary widely among individuals who are undertaking CAS. Secondly, it depends on their innate cognitive and technical skills as operators. We have not focused enough on ensuring that operators who are performing CAS have gained sufficient technical training in the safe and effective techniques that are required to produce acceptable outcomes. In addition, the clinical skills required to manage these patients are essential. Again, in the end, we can only formulate guidelines on numbers, and then we must depend on local credentialing boards, and now on state and federal authorities, to monitor outcomes and to document adequate training, skill level, and acceptable results.

TRIALS AND TRIBULATIONS

It is unreasonable that centers that are able to document that they meet the guidelines for both symptomatic and asymptomatic patients cannot provide CAS treatment to patients because of CMS reimbursement limitations. We must work to remedy this situation. We must complete the prospective randomized trials. Fundamentally, we have to complete these trials if we want the level-one scientific evidence that allows us to offer this method of revascularization with confidence.

All randomized trials have their own sets of problems. The CREST trial has now completed recruitment of more than 2,000 patients. CREST needed 2,500 patients and, therefore, a large number of centers and operators. Whatever the results are, we will be able to say in a very positive way that the CREST data are representative of a broad community experience from the years 2002 through 2008. It may be fairly stated, however, that CREST will represent early technology, evolving technique, and midlevel operator experience.

For carotid stenting, operator experience and technique continue to improve. An article in the *American Journal of Neuroradiology* showed a 2% stroke and death rate in 100 consecutive patients, in whom the technical approach to the CAS procedure was performed without predilatation, allowing the stent to dilate the lesion gently, with no postdilatation. These data suggest that the evolution of our knowledge about the best techniques to use in CAS continues. We have to focus much more on fine-tuning and understanding of technique.

Theron and colleagues in France (personal communication) are investigating the technique of primary stent placement, followed by brief embolic protection (total occlusion balloons) only for postdilatation. Others in Europe have presented data on the value of closed-cell stent designs for soft lesions in symptomatic patients. Our group has argued for a minimal manipulation approach using careful predilatation with small coronary balloons, gentle placement of closed-cell stents, and minimal postdilatation with a single inflation with a small (maximum 5 mm) balloon. Our group has performed more than 3,000 procedures and has a complication rate that is <3% overall and <2% for the younger patients. These techniques have not been used in the randomized trials and certainly not in the recently reported European randomized trials. The challenge for us is to continue these in randomized trials. When we finish CREST, we must focus on the ACT I trial because the level of technology, the technical skills of the operators, and our understanding of optimal CAS techniques are evolving rapidly. When ACT I is complete, we should start randomized trials looking, in a rigorous way, at comparing

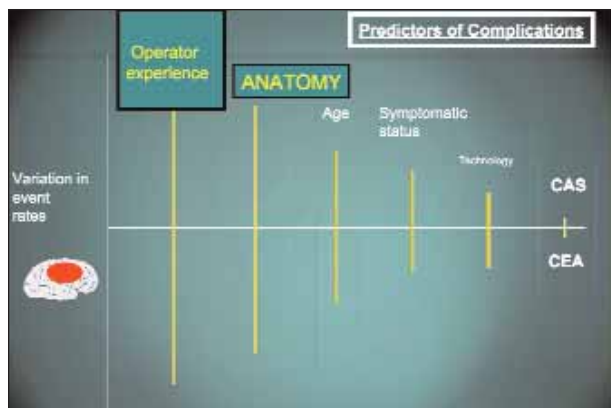


Figure 1. Factors that determine complications from carotid revascularization and relative importance.

one technical approach to another. We must now start planning for funding of CREST 2. This prospective study should analyze outcomes with a more refined patient selection protocol and updated technical approach. That approach will give us data on whether we should use predilatation or postdilatation, whether we should leave the stent to dilate by itself, what size balloon we should use, and which embolic protection device we should use. But our current focus is elsewhere.

We are still trying to compare CAS—in its rapid phase of evolution—to CEA, which is perfectly appropriate, but not a stopping place. The challenge is to finish CREST, examine the data, understand where we are with CAS outcomes from 2002 to 2008, and look beyond 2008 to ask ourselves how we can further refine the stents and other devices, as well as the technique. Greater physician experience will generate greater understanding regarding proper patient selection (eg, that highly tortuous aortic arches and carotid vessels are not appropriate for stenting, and that heavily calcified lesions in elderly patients, particularly if they are very tortuous, are not appropriate for stenting). Factors that determine complications from carotid revascularizations and relative importance are shown in Figure 1.

SPECIALTY-SPECIFIC BARRIERS

Each specialty brings a different skill set to the table in terms of clinical, cognitive, and technical skills. I am confident that regardless of whether the background training is in vascular surgery, interventional radiology, or interventional cardiology, physicians who take the time to participate in programs in which sufficient numbers of CAS procedures are performed can develop the required clinical, cognitive, and technical skills. There are some operators, regardless of discipline, who will never develop the skills. This is probably true for all procedurally based interventions.

Interventional cardiologists with extensive experience have the cognitive skills associated with the treatment of the carotid and cerebrovascular vessels, but they still need to develop the appropriate neuroradiologic skills to ensure patient safety in CAS procedures. The neuroradiologists need to develop skills in the use of the embolic protective devices, stents, and balloons they do not usually use for intracranial work. Vascular surgeons clearly understand the disease very well, but they must develop neuroradiologic skills, as well as skills using the fine manipulative techniques and equipment required, for example, in carotid bifurcation.

There are challenges for all three groups, but focused training in CAS is necessary, whether it is undertaken in training programs or by physicians taking the time to develop skills in centers and interventional laboratories where this work is being done. One training method or the other is necessary to produce the results required to match CEA.

IMPROVED OUTCOMES, INCREASED PATIENTS TREATED

It will come to issues of patient selection, operator training, and experience. If we want to discuss barriers to CMS reimbursement, let's first admit that CMS needs to see stellar outcomes and this is a function of good patient selection and good technique producing good outcomes.

Meanwhile, we have well-established guidelines for revascularization outcomes that provide prognostic benefit for symptomatic and asymptomatic patients and CMS should be prepared to reimburse hospitals and operators that meet these objective, easy-to-measure, objective performance standards.

I believe that we will ultimately demonstrate that for approximately 80% of patients requiring carotid revascularization, CAS will be the procedure of choice; there will always be a role for CEA because even with the most finely tuned technical skills, there are still patients who are much better candidates for CEA. We are currently looking at a series of 1,500 patients whom we have triaged carefully during the last 3 years to CAS and CEA. The outcomes in both CAS and CEA are stellar. We hope to have this paper prepared soon to help document that the careful use of these techniques and appropriate patient selection offers the best revascularization outcomes for patients with carotid artery stenoses. ■

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