

Where Is Carotid Stenting Today?

A discussion with Dr. Christopher Metzger on the available data, reimbursement, and industry efforts surrounding this procedure.



Christopher Metzger, MD, is a practicing interventional cardiologist at the Wellmont CVA Heart Institute in Kingsport, Tennessee. He has disclosed that he is a paid consultant to Cordis Corporation, and he has received speaking and symposium honoraria from Abbott Vascular, Spectranetics, Bard, Boston Scientific Corporation, and TriVascular; and hands-on proctor fees from Abbott Vascular and TriVascular. Dr. Metzger may be reached at cmetzger@mycva.com.

Dr. Metzger, can you please share with us your perspective on the carotid stenting landscape today as opposed to 10 years ago?

There's good news and bad news regarding the landscape for carotid stenting. The good news is results of carotid stenting procedures have improved steadily and dramatically over the last 10 years, as all of the clinical trials I am aware of show. Even in high-risk endarterectomy patients (those patients we know don't do well with carotid endarterectomy), we are now seeing stroke and death rates < 3% for asymptomatic patients and < 6% for symptomatic patients. These results also tend to be better than reported in most trials. Furthermore, proximal protection is now available, which further lowers negative outcomes in high-risk patients, like the elderly and symptomatic patients.

Over the years, these results and subsequent experiences have grown into a large knowledge base of lessons learned. This has led carotid stenting practitioners to a better understanding of who needs to be treated and who should not be treated with this interventional procedure. This, in turn, has continued to lower the complication rates and improve techniques.

So, our technique is better, our judgment is better, our equipment is better, and the results, in multiple real-world trials, clearly show carotid stenting is improving and does at least as well as endarterectomy. We have also

demonstrated clinical equipoise with carotid endarterectomy in two randomized published trials (the CREST and SAPHIRE randomized trials) and a third North American rigorous trial as seen in the roll-in patients studied in ACT I (after preliminary signals). This is the good news.

So, what's the bad news? The bad news is, despite all the clinical and data advances, reimbursement coverage is still restricted.

Aside from the SAPHIRE randomized study you mentioned, what can you tell us about the SAPHIRE Worldwide registry?

I was a Co-principal Investigator for the SAPHIRE Worldwide registry, and it was a privilege to be part of the largest carotid stenting trial with 21,000 patients. The included patients had cardiac enzymes tested after the carotid stent procedure, and they all had independent neurologic assessments at baseline, discharge, and at 30 days. The first 10,000 patients of the registry also had a 1-year follow-up.

Thus, the SAPHIRE Worldwide registry was a real world study with 21,000 carotid stent patients with careful prospective adjudication. Results for 15,000 patients have already been publicly presented, and the full 21,000 patients' data set is expected to be presented later this year.

How do you feel Cordis Corporation has contributed to providing a treatment option for patients suffering from carotid artery disease?

I think Cordis Corporation has done a tremendous job supporting carotid stenting and education in carotid artery disease. Not only did they sponsor the SAPHIRE randomized trial, which really launched industry enthusiasm, but Cordis also created and implemented CORDIS CASES® (Carotid Artery Stenting Education System), where they taught people how to do carotid stenting in a highly systematic manner. They followed on to launch SAPHIRE

Worldwide, the most comprehensive study for carotid artery stenting.

Cordis Corporation also has a fantastic stent, the PRECISE® Nitinol Self-Expanding Stent, which has an autotaper feature that works beautifully. In my opinion, this is by far the best stent to use if you are stenting in tortuous anatomy. In addition, the ANGIOGUARD® Emboli Capture Guidewire System has the shortest basket length of any distal protection system and it comes in multiple sizes.

In your words, why do you feel the current information available on the success of carotid stenting has not led to an expanded reimbursement?

There are several reasons for that. First, there is concern that if you have inexperienced operators performing carotid stenting, the results may not be equivalent to those seen in the various trials.

In addition, I believe there is too much of a turf battle between various subspecialties. In other words, there has not been adequate cooperation between interventional cardiology, interventional radiology, vascular surgery, and neurosurgery.

Finally, some authors have cited controversial non-randomized, retrospective “studies,” which do not have independent neurologic endpoints, and include primarily low-risk patients with moderate disease. These have further muddled the reimbursement waters. For example, most physicians would not and should not stent a carotid patient with only a 50% stenosis. We all need to remember that it’s all about the way you’re measuring results and who you’re measuring.

Unfortunately, all of this has started to form a downward spiral with industry. The medical community is losing their interest for it, industry can’t support it, CMS won’t reimburse it—it’s a somewhat vicious cycle.

Currently, I would like to see the reimbursement decisions change. Carotid stenting has been extensively studied and has been shown to be safe and effective and equivalent to approved carotid endarterectomy in appropriate patients. Nowhere else have we seen a procedure that continues to get better, with results that are equivalent to a procedure with higher morbidity, but cannot get reimbursed until the more invasive procedure is turned down. This is where we are right now.

What would you recommend to industry to continue the fight against carotid artery disease?

In every meaningful manner, the industry should continue ongoing education for carotid stenting. Secondly, I think it’s going to take a public awareness campaign as well as collaboration between the subspecialties and industry to petition for the acceptance of carotid stenting at the CMS level. I think we need to set performance standards very high and tie reimbursement to meeting these standards.

If we can’t come up with that kind of collaboration between specialties, industry, and our government payers, we risk losing access to an outstanding technology which could be beneficial to a large number of patients who would be best served with this procedure. ■

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