

Considerations in Shared Decision-Making in Carotid Disease

Dr. William A. Gray, MD, discusses patient selection among carotid treatment options, incorporating contemporary evidence into patient conversations, and balancing physician recommendations with patient preferences.



How does your practice handle clinical decision-making prior to patient discussion (eg, meetings, group setting, one-to-one)?

Our practice is not set up to evaluate every patient from a multidisciplinary perspective, but we do have multiple interdisciplinary meetings

to talk about our broad approaches to various patient population subsets. One of the things we're tackling now is determining the best approach for a patient who has an asymptomatic carotid lesion but needs cardiac surgery. So, while there's not a lot of conversation specific to the patient in front of us, there is a broader conversation about how we think we're going to apply these therapies in specific patient subsets. And that may apply to the patient in front of us. In cases of uncertainty, we bring in other team members or refer the patient.

To get a baseline, what are your key indicators of a patient's suitability for transfemoral carotid artery stenting (TF-CAS), transcarotid artery revascularization (TCAR), carotid endarterectomy (CEA), or medical management alone?

This is a great question because it really requires that the carotid operator be reasonably familiar with the options as they pertain to the patient. Specifically, what are the benefits, what are the risks, and why is that alternative potentially favored or disfavored? The good news is that, for the most part, the long-term outcomes for most revascularizations are equivalent. So, we're really talking about the short-term safety profile of these various options. Let's start with medical therapy, which is a longer-term option conversation. There are patients for whom medical therapy is not even part of their thought process. On the other hand, there are some patients who are very reticent

to have a procedure or surgery, and they'd rather take a chance on medical therapy. You have to feel the patient out.

Sometimes, I ask the patient that question directly. What's your attitude toward these things? When it comes to revascularization strategies, I believe that today, we should probably follow the same paradigm we do for other therapies: least invasive to most invasive, assuming similar safety and efficacy. Because the most invasive therapies generally carry with them adjunctive adverse consequences, they may not necessarily be the right choice for the patient.

In that paradigm, I start with TF-CAS, which, in my opinion, is the least invasive. As CREST-2 demonstrated, it is at least on par with, if not slightly superior to, CEA in asymptomatic patients. My sense is that if the patient is an appropriate candidate, we should offer TF-CAS, and if that's unavailable, then we consider TCAR. If neither option is appropriate for the patient, then they should have the opportunity to take advantage of CEA. The factors that push me to one or the other are really the lesion characteristics and access. So, if the lesion is too tortuous, if the access vessels are too tortuous, if there's too much tortuosity distal to the lesion such that they couldn't place a filter, or if the vessel's heavily calcified in a way that I don't think will allow adequate stent expansion in a safe fashion, then that patient generally is not going to be a candidate for TF-CAS.

If the issue is access tortuosity or type III arch, but the lesion itself and the distal vessel are not accessibly tortuous, then TCAR would be a better option than TF-CAS because it doesn't have to involve the arch as access. If the issues are related to stenting generically (TF-CAS or TCAR), calcification, tortuosity, or lesion length, then I would move to referral for CEA.

Apart from these anatomic considerations, of course comorbidity is also a consideration. Patients

on oxygen with significant advanced coronary disease or heart failure would not be ideal surgical candidates. Accordingly, we may tolerate some of these less attractive anatomic features to the extent that we think that would be safer than subjecting them to surgery.

How has your informed consent process evolved since the Centers for Medicare & Medicaid Services National Coverage Determination (NCD) requiring shared decision-making and discussion of various treatment options? And, what effects have the CREST-2 trial findings had on your discussions?

I've always embraced the shared decision-making model, and I don't think the NCD or CREST-2 has changed my approach to patient discussion. I think that is part and parcel of not being paternal in the physician-patient relationship, that patients should be involved to the extent that they can be. Some of these patients, either from an emotional or cognitive standpoint, have difficulty grasping all the issues, and their families can sometimes be very helpful in that regard. For the most part, I never press somebody to make a decision in the room; they can go home, talk about it, call me back, and we can answer any subsequent questions they have.

Having said that, there are a lot of patients who look at me and say, "Whatever you say, Doc." I push them a little bit, trying to make my best case for them to contribute to the decision. But in this scenario, I will tell them what I think they should have and review why I think they should have it, which is another form of shared decision-making.

The modern carotid data landscape is increasingly diverse and robust, with randomized data and findings from a key landmark trial in CREST-2 now available. Still, opinions among top carotid experts vary and likely will for the foreseeable future. How then can these data be presented in a straightforward fashion for patients while not skewing to the operators' preferences?

This is incorporated in my talk track with the patient. Some patients want to read the paper, and I'll give it to them; some just want a distillation of the results. For the patients in between, I'm happy to say that there was a recent trial where we tested the effectiveness of stenting, surgery, and medical therapy and provide the results in general terms.

Then, we discuss their age relative to life expectancy; for example, if they are 67 years old and have a 10- to 20-year life expectancy, I'll note that medical therapy is probably not the best option due to the risk of stroke over time, whereas with TF-CAS or CEA, the stroke curve generally flattens out pretty significantly. I think this is something that most patients can understand.

Unless the patient specifically asks, I won't get into absolute or relative comparative risks and instead focus on the up-front procedural risk and any associated adverse events. The long-term benefit is equivalent across the therapies, and patients are usually reassured by that.

TCAR is a popular option with data support from a variety of robust pre- and postapproval studies and years of clinical experience; however, it was not one of the arms of CREST-2, and there haven't been randomized evaluations. When discussing this option with patients, is the lack of randomized data a factor?

The larger perception is that TCAR is probably on par with TF-CAS and CEA in terms of long-term efficacy and shorter-term safety. It is difficult because there are no randomized trials, but there's enough experience. The Vascular Quality Initiative data set, as flawed as it may be with the selection and ascertainment bias, probably gives us some directional information about the applicability of TCAR in this patient population. So, if I were to get into an academic discussion about it, I certainly could debate it, but I don't do that in front of my patients. I really talk about it as more or less equivalent choices, depending on the patient's anatomy and situation.

We know that randomized trial outcomes and those in the real world differ, especially when it comes to operator experience. How do you weigh options with patients considering that the team or operator may have significantly more experience and comfort with one procedure versus another?

I'll generally tell them that I have a long experience with TF-CAS and provide how many I've done in my career and how long I've been doing it. If I end up having to refer a patient to a TCAR or CEA team, which is generally the surgical group, I also reinforce that they're experienced, very good operators, and I trust their work, and that I think that they would do a better job with that particular option than I would.

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How would or do you handle scenarios in which your professional opinion disagrees with the patient's state of preference?

If the patient has a strong preference for TCAR or CEA, and I think that it's more or less an equivalent choice between the therapies, then I would validate the patient's choice. On the other hand, if they absolutely do not want surgery but have a 3-cm, heavily calcified, tortuous lesion, I would tell them that I think they're putting themselves at high risk and that I'm not likely to be the operator to do that procedure, because I'm not willing to subject them to that risk; I then advise them to look at good alternatives. In the extreme case where I really think they're making a bad choice, I would try to move them toward the better choice. However, in most cases, the patients we see can be treated by any one of these three therapies successfully and safely. ■

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