CAS Accreditation Roundtable

Our panel of experts discusses the issues and controversies surrounding carotid artery stenting, which is expected to be approved in the near future.

PANEL

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Should cerebral diagnostic angiograms be a prerequisite to carotid artery stenting accreditation? If so, how many?

Dr. Katzen: I believe cerebral angiography is an important prerequisite for carotid stenting. It's basically a fundamental application in essentially a new territory, with new physiology and a new end organ compared to all other types of intervention. Many specialists, outside of those in neuroscience, have no prior training, either in anatomy or the negotiation of vessels and the particular behavior of vessels when they are interfered with by catheters and other types of devices. I believe very strongly that cerebral angiography is necessary on clinical grounds. Furthermore, essentially all existing credentialing criteria rely on a foundation of catheter skills in the circulation in which treatment is going to be provided. So, I think just as a fundamental of the way credentialing documents and training and education is conducted, it relies on some basic experience in navigating, obtaining information, and interpreting information though the performance of diagnostic procedures in that area. In terms of the numbers, I think it's reasonable to say that there's a published document that came out from the neurology and radiology communities asserting that 100 cerebral angiograms were the minimum number recommended prior to moving into intervention. Some are discussing numbers as low as 20 or 30, which I believe came from several variables, including an ongoing ACC/AHA document that is still in the "review and dialog" stage.

Dr. Gray: I agree with all the points that have been made. The problem is that there is a paucity of angiography being done now based on the fact that the noninvasive imaging is so much better than it used to be, and that we can operate and/or stratify patients with CTA or Dopplers. So, where are these people going to get their experience? The second concern is that in none of the trials, including CREST, were there any angiographic criteria to help us or guide us in how we should set a number. I think the number of 25 or so is probably the right number just to get catheter skills and understand what the catheter options are, in terms of the shapes, the reverse curves, and so on. Operators need to be able to dictate the anatomy, understand what they did, what they saw, what they weren't seeing, and all of the pertinent pathology and anomalies.

Dr. Ohki: In general, I agree with what you're saying, but are we trying to create a neuroradiologist here? For example, if I perform a carotid stenting and I do a cerebral angiogram, I know the basic anatomy and what it means. But, if I find a brain aneurysm or an A-V malformation, it is well beyond my capability and, therefore, I would quit right there and send the patient to a neuroradiologist.

Dr. Katzen

"I believe cerebral angiography is an important prerequisite for carotid stenting."

Dr. Gray: You're exactly right, but the point is that one needs to be able to identify that you saw it, and take appropriate next steps to address it.

Dr. Ohki: So, we all agree that we don't have to be as good as a neuroradiologist in doing cerebral angiograms, right?

Dr. Gray: Correct. Let's agree about that.

Dr Ohki: All right, so it's a basic ability that we need to accomplish. One of the problems that I have with the neuroradiology "Quality Improvement Guideline for Carotid Stenting" document that came out in *AJNR* and *JVIR* (*JVIR* 2003;14:321-335) is that they are requiring full-scale training on intracranial angiograms before embarking on carotid stenting, and there is no separation between a fully trained intracranial angiographer and a guy who just wants to do the carotid and know the basics.

Dr. Katzen: The precedent comes from the COCATs document and the ACC documents, which require 300 diagnostic catheterizations before someone can become qualified to be an interventionalist. Three hundred seems like an extraordinary number to be able to do and interpret something that has essentially two vessels and a bunch of branches. The people making that argument are ludicrous.

Dr. Ohki: Three hundred is for somebody who just walked off the street and has never touched a catheter. Here, we are talking about experienced interventionalists

with pre-existing catheter skills in other parts of the body.

Dr. Gray: If you presume that the entry criterion to even talk about doing carotid stenting is that you're an accomplished interventionalist (either peripheral or coronary) with high volumes and that you understand angiography and the basic tenets of intervention, balloon selections, stents and so on, then I agree that 100 is not where we need to be—I think it's closer to 25. Three hundred is really a fellowship training level number.

Dr. Katzen: Should we, collectively as organized medicine, be trying to define basically optimal and minimal qualifications? Essentially, there is a body of work and a body of physicians, (relatively small) who have advanced catheter skills in cerebral angiography, both diagnostic and technically. It's the equivalent of someone saying, I don't want to be as good as a vascular surgeon, I just want to be able to do cut-downs and get access, to be able to be certified to do vascular procedures. Right now, I think we don't really have training and credentialing vehicles to do that, so should we be thinking or talking about stratifying training in some way?

Dr. Ohki: I think so. I think the old model of fellowship and residency does not apply to carotid stenting and this new era, and we should be thinking about a better way to train physicians in a specific, targeted manner.

Dr. Gray: Well, I think we can say that there are really two groups of people that we are talking about. One group is the fellowship trainees who will have to go through the usual accreditation criteria for training, which is already well-established. What we're really talking about here is the first 2 to 4 years of carotid stent training for physicians already in practice because after that, we'll have fellows coming out knowing how to do it as well.

Dr. Ohki

"I think the old model of fellowship and residency does not apply to carotid stenting and this new era."

Dr. Katzen: What about outcomes? Should we be doing (especially with such low numbers) something that the CREST trial has employed, in which they basically require you to do a certain number of cases, but, if you get a certain percentage of cases with adverse events, they double you up or say you've got to do 10 more? Especially when you move down to the lower level, maybe we (I mean all of us who are influencing this field) should put a caveat, maybe for the first time, we should specifically indicate performance parameters so that there is a certain number with a specific minimum performance parameter.

Dr. Ohki: In the *JVIR/AJNR* document, there is a very nice criterion whereby a review is initiated once you hit a certain complication threshold. That's the only part that I agree with this document, by the way. They have major stroke, reversible stroke, permanent stroke, and they have stratified into asymptomatic patients, symptomatic patients; if you hit 3.5% with asymptomatic, then you are subjected to review. I think there should be some mechanism whereby one's competence is checked on an ongoing basis.

Dr. Katzen: What about physicians who are currently in the vascular arena, like vascular surgeons who have had no endovascular training but who are interested in getting into it—and the carotids represent the wake-up call to them? Who is going to look out for quality as we take people from ground zero?

Dr. Ohki: Stroke prevention is what we're talking about, not stroke therapy. If a patient comes to the ER with an acute stroke, vascular surgeons do not get involved. Vascular surgeons, actually all of us with the exception of the neuroradiologist, are involved in stroke prevention, and I think we should separate the prevention from the stroke therapy. In terms of stroke prevention, I think we can simplify the training process very much. For the vascular surgeons who are performing carotid endarterectomy, we are well positioned to do carotid stenting because the vascular surgeons do go through the cognitive knowledge training of basic stroke evaluation, we do take care of postoperative hyperperfusion, hypertension, and other issues associated with carotid endarterectomy, all of which are also fundamental in performing carotid stenting. But we are not trained to take care of stroke, and we do not need to. Vascular surgeons already possess many of the skills and

knowledge needed to do carotid stenting, with the exception of catheter skills.

Dr. Gray: The bigger question is someone who has no 0.035-inch wire skills or very rudimentary skills. I think those people need to go back and get fully credentialed in peripheral vascular intervention and have a body of experience that they can put up as representative experience to qualify them as interventionalists.

Dr. Ohki: I'd like to say that endograft experience should not count.

Dr. Gray: I agree.

Dr. Ohki: By the same token, coronary intervention, PTCA, should not count.

Dr. Gray: Whoa! Whoa! I do both of them, Tak, and I can tell you, there's a huge difference. In fact, our fellow just finished his vascular surgical fellowship and came over and did endovascular work for a year. He just finished and he's a very good interventionalist now. I asked him what was the number one thing that made him the good interventionalist that he is now. He said being able to do coronary interventions. He said that doing the coronary interventions was what gave him the security and expertise he needed with wires, balloons, and stents and it translated well into PAD intervention. It is a huge advantage that cardiologists bring to the table.

Dr. Ohki: I do agree that there is more overlap between PTCA and carotid stenting, but PTCA is still quite different from carotid stenting.

Dr. Gray: They still need to be peripherally credentialed.

Does everybody need to be a neurointerventionalist from the training and qualification point of view to do carotid stenting?

Dr. Murphy: We don't have to be neurointerventionalists. I think that the credo has to be that the patient must be equally safe in all hands because the patient doesn't understand the difference between us. We have to offer a pretty much uniform level of service. Also, we have to be awfully careful deciding what is an appropriate number of cases because I've seen fellows who are clearly talented from the very beginning; they obviously have talent, and within 10 and 15 cases you can see that they will be safe. I've seen others who, at the end of a year, are still klutzes. So, the human element of this is going to be very hard to regulate. The insight that people need in order to do this safely is going to be hard to regulate.

Dr. Smith

"We're not trying to be exclusive; we're trying to be inclusive. We want people to do this [CAS] as long as they meet performance guidelines ."

One of the critical things the cardiologists bring to the table is fundamental skill sets with catheters and wires. They're very comfortable with innominate internal mammary access, and they begin with an advantage over most people in vascular surgery who don't have those skills. Endografts are quite fundamentally different in terms of the tolerance of the end organ to injury. In terms of stroke therapy, I think there are fundamental salvage skills that need to be known by people to get themselves out of trouble. The thing that I would like to emphasize to those who want to enter this field for the first time is that their teachers exist internally in radiology; they should build relationships internally. Going to courses run by Cordis or anyone else on angiography is great, but if we could accomplish a better sharing of knowledge within the buildings in which people currently are, we would probably be able to accomplish a standard skill set quicker than people trying to learn in isolation of each other.

Dr. Katzen: It is an interesting thought, in that regard. What if some of us were to create a board to actually certify people on these simulators? The board would give someone a test to interpret a combination of cerebral angiograms and to perform, at some technical level, a carotid stent procedure, perhaps on the simulator. The board would then certify that person if they met the qualifications.

Dr. Smith: That's a good idea, but I think that your performance standards also contribute a lot and it sort of kicks it back to the local authority. So basically, your level of expertise is assessed and monitored locally. We can give minimum performance standards whereby the vascular surgeon doesn't need to perform at the level of a neurosurgeon. However, he should have a fundamental knowledge of intracranial circulation and flow.

Dr. Ohki: Most vascular surgeons do have that knowledge, because when we do carotid endarterectomies, maybe not now, but 5 years ago, cerebral angiography was part of the treatment, so we are used to reading cerebral angiograms. So, by and large, vascular surgeons are quite familiar with these basics.

Dr. Katzen: As an interventional radiologist, I have had the opportunity to perform do a lot of cerebral angiography in conjunction with our neuro folks, and I have found working with a neurointerventionalist and looking at the completion angiograms from carotid stenting to be much more in depth. I've really learned a lot. The subtleties of looking at cerebral blood flow in regional areas is much different than simply looking for occluded arteries.

Dr. Murphy: I don't want to be an elitist. I think you're right, there are things we might find because we see so many. One thing that I'd like to say is that we need to be conscious all the time of separating marketing from science. We need to look at who is producing this scientific data, what their end goal is (which is to sell devices), and make sure that we're doing the right thing for the patient. I still think that carotid endarterectomy is an excellent procedure, and I think that the margins of benefit for stenting over endarterectomy are relatively slim. There is an evolutionary trend in a certain direction. I have doubts about the benefits of distal flow protection devices. I've been reviewing some papers for *Radiology* recently, and they include large series indicating that complication rates are higher than anticipated from their use, and we have to really work hard to make sure that we give our patients truly informed consent in this setting. We must help them overcome their fear of endarterectomy and neck surgery, and we must advise them about the right procedure for them.

Dr. Gray: If one believes we've achieved equipoise, that these procedures are relatively closely aligned, and experts won't be able to tell the difference between them in any significant way, then we can offer them to patients in a randomized trial like CREST. And we should present it in that manner to the patient, as relatively equivalent choices. However, for any individual patient, risks may be higher for surgery; SAPPHIRE showed that in a dramatic way. Patients will make decisions relative to how things are presented to them, but also to what they hear on the street and in the news. We could argue about a percent here or a percent there of a stroke risk between the procedures, but when it's all said and done, when the total risk is less than 5% and the patients know that the options are pretty close, they are going to choose the nonsurgical route more often. We see that in our practice here.

Dr. Murphy

"We need to be conscious all the time of separating marketing from science."

Dr. Ohki: I agree, and because of that, I think that we should think about the fact that we are not training physicians for a very special procedure. This is going to be a "bread and butter" procedure, and we have to think about the bulk or the mass of physicians that need to be trained. Certainly, a few hundred interventionalists are not going to be enough for the US and, therefore, whatever training recommendation we make has to be practical.

Dr. Katzen: I think Dr. Murphy raised a great point that the patient needs to be confronted with an equal chance of success, regardless of who's treating him. I wanted to ask Dr. Smith two questions about this: From your point of view as a vascular medicine specialist, what is your take on some of the disputes and concerns we have over the training and credentialing as you see this new procedure, and do you think there's any role from the public health point of view of reinforcing the consumers or the patients to make sure and ask their physicians what their experience is and what the outcomes are?

Dr. Smith: They are two good points, but I still think that the onus lies on the local expertise and performance indicators.

Dr. Murphy: I think you're right; informed consent will vary from center to center depending on whom the choice is between. The expertise in the specific place is what matters, not what happens in the literature.

Dr. Smith: And also performance standards.

Dr. Ohki: I did say that endografting is radically different and that particular experience should not count, and I think there are a lot of similarities between renal angioplasty and stenting, as well as SFA angioplasty and stenting and carotid stenting because of the use of the 0.014-inch and the 0.018-inch systems, use of self-expanding stents, and the use of guides and sheaths. I think that experience, the number of SFA/renal angioplasty and stenting procedures, should be a prerequisite to enter into any carotid training program. I also think that the same criteria should be applied to radiologists and cardiologists.

Dr. Smith: If that's going to make for a low threshold for vascular surgeons, that's fine, but it still falls back to performance standards.

Dr. Ohki: But we have to start somewhere.

Dr. Smith: Of course. We're not trying to be exclusive; we're trying to be inclusive. We want people to do this as long as they meet performance guidelines.

Dr. Katzen: Generally, credentialing documents don't really say anything about outcomes. They just say you have to complete it with satisfactory results, whatever those are. We should be working a little bit harder on defining and unifying expected performance outcomes, especially for carotids, because the benefit of carotid intervention, whether it's surgery or stenting, is predicated on extremely low morbidity rates, to really achieve statistical benefit in stroke protection.

Dr. Ohki: We all agree that having peripheral endovascular credentials is prerequisite number one, as outlined by the AHA.

Dr. Murphy: Well, that would exclude all the neurointerventionalists.

Dr. Ohki: Ok, with the exception of neurointerventionalists.

Dr. Smith: Let's say, "minimal standards."

Dr. Ohki: In terms of SFA/renal angioplasty, do you think that's a good starting point for selecting physicians to participate in the training program?

Dr. Katzen: To have peripheral vascular experience? Yes, I've had SFAs, iliacs, renals; that's a platform on which to build before you engage in cerebrals.

Dr. Ohki: Because carotid stenting is not an entry level procedure, I would say 30 to 50 SFA/renal cases would be a good number to achieve before going on to the next step, which would be carotid/cerebral angiograms, and we've talked about 30 to 50 instead of 100 carotid angiograms.

Dr. Katzen: Well, I think that it suffices to say that this panel wouldn't agree on a number for the purpose of the document. I think that the numbers have ranged from 100, which has been published, to 30 on the low end, and about 50, which I think is being considered by the AHA right now. Maybe I could ask you your opinion on this, Dr. Murphy. I'm dealing with this myself now. Given the reduction in cerebral angiography in general, outside of the neuro, the need for arch and carotid angiography when the traditional interventional radiologist would have gotten the experience, is 100 cerebral angiograms going to be realistically achievable outside of a neurointerventional fellowship?

Dr. Murphy: I think it would be really hard, for example, our peripheral interventional labs do about 14,000 exams per year, but they probably only do about 60 to 80 cerebral angiograms. Also, they have six fellows. It would be very hard to achieve that.

What percentage of one's total experience would you feel could be accomplished through simulators, assuming that there is an ideal simulator?

Dr. Murphy: I've played with the Mentice simulator quite a lot; I worked with Cordis in getting it running. I would think 10% to 20%. A lot of it has to come from the prudence and judgment and the tactile skills and finesse that you get just from using catheters. The thing that we do with our fingers but we find hard to explain to others. That doesn't have to be in the neuro area. I think that we have to involve neurologists in this as well because they want to be involved to teach us indications for these things. We need to know how to do rapid stroke exams that we can use on the angio table. All of that has to be factored into the training so that we can do this prudently.

Dr. Katzen: What role should medical simulation play in the accreditation process?

Dr. Gray: I think it's going to serve a purpose in several ways. First, it will give us an opportunity to stratify people regarding entry into different training programs. For instance, someone may say he knows how

Dr. Gray

"Simulation hasn't been embraced completely because it hasn't been widely tested against real-life experience."

to do X, Y, or Z, but when he gets on a simulator, he can't do anything. Second, it may be a very valuable teaching tool, both in regard to angiography, as well as for people for intervention. It's helpful because there is no live patient, so you can stop the procedure and give specific caveats, choices for the interventionalists, and situational changes that the simulation device itself may not give you, but that you can talk about in real time. With a real patient, there's a pressing need to get the filter in and then get it out in a timely fashion. There's not really time to talk about it during the procedure. With a medical simulator, all of those variables and learning caveats can be preprogrammed, especially in challenging cases, which is where I think the simulator may be most useful.

Dr. Katzen: Do you have any thoughts on what percentage of one's total experience might be able to be achieved through simulators or that organized medicine should recommend to be achieved through simulators versus live patients?

Dr. Ohki: Having played with various simulators, I think there are two distinct approaches. For example, the Mentice is more of a hand-eye–coordination, tactile skills training device, whereas the SimSuite focuses more on cognitive knowledge and judgment. In light of these variances, I think that different specialties will have to select different devices.

Dr. Gray: One thing I'm coming to understand is that simulators can actually measure movement, down to the second; which way you turn the wire, if you advance it, if you pause, if you do the wrong thing with the wire in the wrong vessel, etc. Metrics can be assigned to these variables. What you and I would look at as a subjective evaluation of the performance of the operator can actually be quantified very objectively. Again, not only can you stratify people on the entry to these programs, but also on their exit.

Dr. Katzen: Everybody seems to be embracing simulators for training technique, but should we really be talking about using simulators for testing technique? In addition to the training advantage, the ability to test operators could be beneficial. If someone wants to become credentialed at a specific hospital, maybe they would have to receive specific training in whatever those criteria are, but maybe hospitals can require specific testing of physicians on a continuing basis. Simulators also offer that as a tremendous opportunity.

Dr. Gray: There are huge opportunities and strengths, but one of the limitations to simulation right now is that it has not been ratified by independent testing. The reason why simulation hasn't been embraced completely is because it hasn't been widely tested against real-life experience in this application [endovascular training]. However, simulation has done very well in other applications. There is still some work to do in getting training accomplished through simulation as compared to standardized training.

Dr. Ohki: We've all talked about the technical aspects, but how about the cognitive knowledge required for training? Should we just dump that all on the neurologists and know nothing about stroke syndromes?

Dr. Murphy: Certainly not.

Dr. Ohki: We all agree that we need to have some level of cognitive knowledge.

Dr. Smith: It's very easy to get certified on the NIH stroke scale online.

Dr. Katzen: Everyone agrees that there does need to be some discussion about cognitive knowledge associated with doing these procedures.

SUMMARY REMARKS

Dr. Ohki: Carotid stenting is probably going to be a "bread and butter" procedure in the near future, and when we talk about training, we should keep in mind that we have to train a lot of physicians. We certainly do not need to become a combined neuroradiologist, neurologist, and a surgeon for carotid stenting. We just have to take bits and pieces of the basic principles that are needed to complete the puzzle. If we focus on what

is really essential for carotid stenting, I think that the training program can be streamlined, narrowed down, and not be too excessive such that we will be able to meet the large demand that is going to come very soon. For vascular surgeons, I think the peripheral intervention experience would be a very good step toward carotid stenting, but I acknowledge that many vascular surgeons need to make a serious commitment and go through proper training before we start mucking around with people's brains.

Dr. Smith: Number one, I think that a very vital part of this is performance standards, which are suggested by us but enforced by the local institutions. In my opinion, simulation training is not where it needs to be. Maybe 30% of the necessary knowledge could be gained from the simulator I was on last week. The amount of knowledge gained can pertain to intracranial anatomy and delivery of the catheter systems, etc., but the simulator is not where it needs to be. I agree strongly with Dr. Ohki that if you accumulate all of your knowledge and experience on peripheral vascular cases, not necessarily stent grafts, you should qualify to at least pursue carotid stenting. The caution I've given my local surgeons is that the learning curve is very, very steep, and in my opinion, the hardest part of this is getting the delivery system in place. Once you get the delivery catheter placed, you're pretty much in good shape. Insofar as understanding and recognizing complications go, you must have a neurologist interact with you, someone who can give you clinical assessments and judgment.

Dr. Ohki: So you don't have to be a neurologist yourself?

Dr. Smith: No.

Dr. Katzen: But you need to have some sort of integrated team capable of providing complete care.

Dr. Murphy: I agree with the comments about the simulator. I think they're promising but they're not there yet. The data sets of cases and shapes of carotid bifurcations, of aortic origins and vessels are not installed on them yet. But they do have promise, and perhaps we'll be able to get to a point quite soon where there would be something that we could bring home and work and train in our basement. I agree that we need performance standards. We need reporting of those standards, both regionally and nationally. We need to avoid the same approach to this disease that we've seen with vascular surgeons versus neurosurgeons with carotid endarterectomy. I think it's important to be aware of complication rates. I personally fear the same thing that happened with LASIK eye surgery, which was initially very promising, and then it became a popular, procedure nationally, at which point the standard fell off. Now it's found a natural balance in the community and in its place in our care for patients. If those things happen with carotid stenting, however, there will be a huge number of strokes. This issue of informed consent is so important because it will depend on the skill set available at that particular site on that particular day. The risks a patient will face will depend on that. The emphasis needs to be on the sharing of knowledge in institutions to make sure that everybody who has something to add to that procedure can be present and that the relationships between people in individual sites can be good enough to allow them to communicate well and ask for help and advice, and to apply the best possible collection of brains and neurons to that one particular situation. I think we need a new board to govern our traditional training groups of vascular surgery, radiology, cardiology, neurosurgery, neurology area entry points to training as an endovascular physician. With carotid stenting, we have a procedure that is numerous enough to allow a financially viable career for a new endovascular specialist.

Dr. Katzen: We need to be concerned about the dissemination of this technology. And more than just concern, we need a feeling or responsibility to a patient as we take an experimental procedure and it becomes a reality in the patient community. One thing that I'm concerned about is the whole concept of the learning curve, which has been identified as an issue in carotid stenting. Basically, this translates into numbers of strokes. If you took a learning curve rate and considered it as the stroke rate, I think we all have a responsibility as we train and try to define the training and credentials to do everything we can to make sure that the adverse event rate does not really soar as a result of the introduction of this technology. If there's something we can do to alter the learning curve through better training and better credentialing, I think it's a real critical thing. Hopefully, we'll have an opportunity, because it's such an important area, for all the societies and key medical disciplines to really work together on this. But clearly from the forum's point of view, there's a lot of agreement, although we still haven't gotten to the point where I think we have a unanimous decision on exactly what the training and credentialing should be; we have some general concepts to follow. ■