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Examining Cerebral Embolic Protection

Announcer:
Welcome to ReachMD.

This medical industry feature titled “Examining Cerebral Embolic Protection“ is sponsored by Boston Scientific.

Here are your guests, Dr. Hemal Gada and Vijay Iyer.

Dr. Gada:
I’m Hemal Gada. I am a structural interventional cardiologist at UPMC Pinnacle in Harrisburg, Pennsylvania.

Dr. Iyer:
I’m Vijay Iyer. I’m an interventional cardiologist and structural interventionalist at the Gates Vascular Institute and Buffalo General Medical Center in Buffalo, New York.

Dr. Gada:
Welcome to the Structural Heart to Heart podcast. Today we’ll be talking about cerebral embolic protection specifically as it relates to transcatheter aortic valve replacement. We’ll be going over some of the clinical considerations, the clinical evidence bed, some of the economic considerations with regards to adoption of technology and where we see the future going.

So, Vijay, can we just kick it off with what do you think about stroke in TAVR? Is this a problem? And what are your thoughts around it?

Dr. Iyer:
It’s interesting. We’ve evolved in a thought process about stroke in TAVR from the early days of PARTNER to where we are right now. When we came out of the first iteration of PARTNER, we thought that stroke was a real problem. The rates were pretty high. Since then, the stroke rates have declined, but the reality is that of all the different things we do with TAVR, with all the benefit we create, the most devastating complication is stroke. I mean, nothing changes your quality of life like a stroke, not just the cost of healthcare subsequent to that, but to the individual and the family, it is a huge burden. So, when you look at stroke, while the rates have dropped down, the total number of cases we do have gone up, so in reality, even a single stroke in your center in a year, if you do 100 cases and you have 1 or 2 strokes, which is what you would predict right now—I think it is still pretty devastating, and anything you can do to reduce that rate, especially as we go to younger individuals, I think is absolutely critical.

Dr. Gada:
Vijay, when you think about periprocedural stroke, do you think that the people in our community actually understand the gravity of this problem?

Dr. Iyer:
I’m not sure everybody does. I think to some extent we are to blame just because we have tried to tell people that the risk of stroke with TAVR is declining, it is lower than surgery, but at the same time, even that small amount of stroke is an unacceptable amount in my mind, so anything you can do to reduce it is extremely important.

Dr. Gada:
One of the hot topics are these low-risk patients. So we had 2 large randomized controlled trials, approval of commercial low risk that happened with the FDA just a little while ago. Does that change the role maybe of how you think, or does it change the way you think about stroke in TAVR patients?

Dr. Iyer:
I think with the low-risk trials, while the stroke rates are low, it's extremely important as we start to treat these low-risk patients who are much younger we have to strive to get to a stroke rate that's zero percent.

Dr. Gada:
Yeah.

Dr. Iyer:
I think that's critical.

Dr. Gada:
And what do you think about the body of evidence with regards to stroke and transcatheter aortic valve replacement with regards to neurologically adjudicated stroke versus non?

Dr. Iyer:
Yes. Every trial has had that caveat to some extent. The trials that were not neurologically adjudicated—that means a neurologist investigated the patient before and after the TAVR and examined them—the stroke rates were higher.

Dr. Gada:
Yeah.

Dr. Iyer:
We found the same thing with surgical AVR. When we started to adjudicate the events, we suddenly realized, "Oh my God, the rates are much higher." So clearly not every site does that, and that's why I think some of the numbers in the TVT registry probably don't reflect the true number of strokes—because you're not required to do that...

Dr. Gada:
And regardless, the TVT registry numbers, even with dropping risk indications, the stroke rate has remained the same.

Dr. Iyer:
Remained about the same.

Dr. Gada:
Yeah.

Dr. Iyer:
And, I mean, what we found out is that stroke rates have remained about the same across the risk spectrum. Not only that, they've actually... Stroke doesn't discriminate. You can be an operator who does 50 cases—or you could be an operator who does a thousand cases.

Dr. Gada:
No volume basis.

Dr. Iyer:
There's not a volume basis to it.

Dr. Gada:
Yeah. So, Vijay, tell us about your experience with the Sentinel Cerebral Protection System. When did you start using it? And what was that trajectory like?

Dr. Iyer:
We were not in the clinical trial for Sentinel, but the moment it was commercially approved and the FDA approval and when we saw the data... And actually, for me personally, the most compelling piece was seeing the filters and the debris that you were collecting. Whether you had a clinical stroke or not, I can't imagine clinically that that debris in the brain can be good for anybody.

Dr. Gada:
Right.

Dr. Iyer:
So we decided as an organization and as a team that despite the financial risk that we would go forward full on. Since the trial didn't help us differentiate who would be high-risk and who would be low-risk, we had no scientific basis to say we could use it in this population and not in those.

Dr. Gada:
It really is an all or none type of adoption.

Dr. Iyer:
That is correct. So we decided we were going to do all—TAVR, and our policy since that time has been that everybody who we can anatomically get a Sentinel filter in for TAVR we do it.

Dr. Gada:
When you were making your pitch to administration for adoption of the device, I mean, clearly there's an economic challenge there—because there's no additional reimbursement for most cases so I'm just wondering what was that pitch like for you.

Dr. Iyer:
The economics are always tough, especially early on, because contribution margins per case were not very large, uh, so we learned to do a couple of different things. We realized that if we need to have some of these new tech add-ons that we think are important and important for our patients—then we have to tighten up in other places.

That means we have to get more efficient, we have to figure out ways to keep our length of stay down, keep our complication rates down, keep our pacemaker rates down.

So all of that builds into the argument wherein now you can look at the whole picture and say, "This is an important technology that we believe reduces our complication rate, improves the quality of life for our patients, and therefore, it's important." And I did not have much trouble with your administration when we pitched it in those terms.

Dr. Gada:
That's great. And then, did you see a growth in volume of your program at large because of the adoption of Sentinel, or can you relate any type of volume effect there?

Dr. Iyer:
Early on I don't know that we had a growth because it was definitely a differentiator for us—for the longest time, and actually, even now we are one of the few centers that have what we call a Sentinel-for-all policy. We don't discriminate. Everybody gets a Sentinel.

We have had people who come to us specifically with the question, "Hey, you guys I hear use the Sentinel. I'd rather have TAVR at your site rather than go somewhere else."

Dr. Gada:
Right. And was there a dedicated marketing campaign that you used?

Dr. Iyer:
Oh, we never did a dedicated marketing campaign towards patients, but we did focus on referring doctors, referring cardiologists—

Dr. Gada:
Yes.

Dr. Iyer:
—talking about the problem in the context. It's very important to define the context because you don't want the message to be that stroke is a big problem in TAVR.

Dr. Gada:
Right.

Dr. Iyer:
By the same token, you do want to emphasize the fact that your goal here is to reduce stroke rates to minimal to zero.

Dr. Gada:
No doubt. And when you were having that referring provider communication, what are some pieces of data that you may have referred to, or what's that evidence base?

Dr. Iyer:
I think it's important to talk about the IDE trial because you have to start there.

Dr. Gada:
Yeah.

Dr. Iyer:
I think you have to make the point that the important point there with the DW-MRI hits the filter data. Yes, the endpoints were probably not what we looked at, but then, when you look at the volume of strokes and how it's coming down, maybe it's gonna be hard to do that in any trial. By the same token, the question is very simple. When you see the DW-MRI data, when you look at the filter data and you put yourself in the patient's shoes and say, "Do I want this in my brain or do I not?" "If I have a loved one who's gonna have a TAVR—am I gonna put a Sentinel or not?" I think the argument is sort of… You know, you made your argument.

Dr. Gada:
Yeah, right.

Dr. Iyer:
You don't really need to, I mean, make any more arguments at that point, I think.

Dr. Gada:
Yeah, I mean, critical argument though. Okay, clinical data, we can choose to kind of parse that out, and if we look at totality of evidence as it's building, I think there's more and more favor with regards to stroke protection with this particular device, and so...

Dr. Iyer:
And you've done PARTNER with the—your site with Cedars and others—and published that data.

Dr. Gada:
Yeah.

Dr. Iyer:
You know, in addition to the IDE trial, there's now single centers, multi-centers—

Dr. Gada:
Multi-centers, yeah.

Dr. Iyer:
—meta-analysis—

Dr. Gada:
Absolutely.

Dr. Iyer:
—all of which favor the use of protection.

Agreed, we don't have true randomized controlled data yet, but should that stop you from using it? I am pretty sure not.

Dr. Gada:
So then the clinical evidence is one thing, and then the economic impact, which you touched on earlier, so I wanted to dwell on that a little bit. So, obviously we're dealing with limited contribution margins, especially at non-academic medical centers, that are maybe in less affluent areas, where the wage indices are a little bit on the lower side.

I think your center and my center probably share that. And so, I'm just wondering, how does that conversation work?

Dr. Iyer:
I mean, you made that argument very, very nicely in terms of looking at the cost of care, not just for TAVR but for TAVR and its complications.

Dr. Gada:
Right.

Dr. Iyer:
And you gotta ask yourself, "If I'm a center that does 100 to 150 cases and we get 2 devastating strokes, what is the cost of care for those 2 strokes "and how does that impact the institution, not just for that episode of care but for the continuum of care for that individual?"

How is that? I mean, it's not just the acute hospitalization as the ICU stays. It's the subsequent imaging, the rehab, all of that.

What is the cost of that, and how do you factor that into saying, "I could have prevented that"? And what is the cost of prevention versus the cost of actually taking care of the stroke?

Dr. Gada:
Absolutely true. And one of TAVR's greatest strengths is its ability to lean up in comparison to surgery and provide efficient disposition. Strokes would definitely go against that to a large degree, so I think economically there is an argument to be made—

Dr. Iyer:
I agree.

Dr. Gada:
—for the device, so it's very interesting. With regards to the impact of Sentinel clinically at your facility, since you've taken on Sentinel, what type of clinical results have you seen?

Dr. Iyer:
Our stroke rates were sort of in the 1.5–2% range when we first started.

Dr. Gada:
So you were pretty low to start.

Dr. Iyer:
They were pretty low to start.

Dr. Gada:
Yeah.

Dr. Iyer:
But in that transition over the last couple of years, we've gone from a site that in 2011 or '12 we did about 28 cases to this year we'll do more than 400 cases.

So, when you look at that throughput of cases, we've had the same rates of stroke. Actually, our stroke rates are... I can't even remember the last time we had a devastating stroke in the institution. So it has become a—a real rarity. I mean, if it happens it's a big deal for us now.

And if it happens once a year, it's a big deal. Do we have evidence that the Sentinel in every case had... Early on we used to look at the filter in every case, and in every case we used to find it, so we stopped looking. We said, "Okay, that's an assumption we're going to catch something."

Dr. Gada:
Mm-hmm.

Dr. Iyer:
Sometimes it's small, sometimes it's large and we're gonna use it, and our stroke rates are definitely lower than they were before.

Dr. Gada:
Right. At least the rates of debilitating stroke definitely you would agree, right?

Dr. Iyer:
Yes.

Dr. Gada:
And, I mean, I think that that's something that is detectible. And so that brings us to kind of where the field is going. So, with the current data in Sentinel IDE, that did not really get its primary endpoint.

Do you think that future clinical trial work is needed in this field? And what would that consist of?

Dr. Iyer:
I think it's important... I think, yes, I agree, I think it would be great to have randomized clinical trial data because that would help us move into guidelines. I think I do agree with that. By the same token, is stroke the real endpoint we've got to be looking at? I'm not 100% convinced about that because a lot of this microscopic debris may not cause a clinical event which you can recognize as a stroke.

Dr. Gada:
Right.

Dr. Iyer:

But when you have 100 of these particles or a thousand of these particles going into the microvasculature—I wonder what it does to your cognitive ability.

Dr. Gada:
Have you noticed a difference in the acuity, mental acuity, of your patients since using Sentinel?

Dr. Iyer:
Yes, my valve clinic coordinator likes to call it the foggy brain syndrome—or the fuzzy head syndrome.

And she would always tell us that there is this population of patients who come back after TAVR and they are fine; there's no detectible neurological deficit—but they're just off cognitively.

They call themselves; "I feel fuzzy in my brain." I had a professor tell me, you know, "I was teaching, and in the middle of my course, I kind of forgot the material that I had been teaching for 20 years."

Dr. Gada:
That can be quite acute as well. I've noticed that.

Dr. Iyer:
Yes.

Dr. Gada:
It can be quite acute, and then it could also last for some period of time afterwards.

Dr. Iyer:
That's correct. And we have not seen that since we started using Sentinel—

Dr. Gada:
Yeah, I agree.

Dr. Iyer:
—I have to say. We ask this question very carefully, because for a brief period I had a student doing a neurocognitive analysis on every patient—

Dr. Gada:
Wow.

Dr. Iyer:
—pre and post TAVR.

You know, the problem with neurocognitive analysis in an 85-year-old is that sometimes it's difficult to completely do it—as we go to the lower patient population pool. I think neurocognitive evaluation of these patients in a trial is gonna be extremely important, and long-term follow-up is important, because we may not see the results for 2 years or 3 years.

It may be long-term. You know, the cognitive decline may be subtle but definite, and we have to find ways that we can detect it.

Dr. Gada:
Mm-hmm. So put it together for us then. So we've talked about kind of the clinical evidence base, where that evidence base needs to go, the economic barriers to entry, where those economics can kind of be negotiated.

Are there any other pieces to the Sentinel experience that you hold dear as a person? And how has it kind of made you feel about transcatheter aortic valve replacement as a therapy in general?

Dr. Iyer:
If you're an operator of any kind as an interventional cardiologist, you always remember your most devastating complications, right? And for TAVR it's the ruptures and the strokes. Those are the things that I remember the most. You know, we've done 1,500 plus TAVRs, but I remember every patient who had a stroke, and I remember every patient who had a rupture, and it changes how you look at the therapy because you're there to do good, and that's one of those things that really stays with you. To be able to walk into a procedure with the confidence to say that I can take 1 complication off the table—with a device that is simple to deploy, easy to use, not complicated, clearly shown to be safe in the trial, I think that gives you a lot of comfort in doing that procedure. You can walk up to your patients and say, "Listen, I agree. There's a calcified valve. There's a lot of things we can do that can potentially cause a stroke. By the same token, I have a very effective tool that during the procedure that can minimize your risk of stroke." I think that gives you a lot of

confidence as an operator.

Dr. Gada:
That's a great way to sum it up. So, the last question is more of kind of an emotional tilt on things. Describe kind of what you would feel if you had a loved one that was undergoing transcatheter aortic valve replacement and the physician was contemplating using Sentinel or not.

Take me through what that would...

Dr. Iyer:
I mean, I tell my partners, I tell my referring physicians, "Put yourself in the shoes of the person going for the valve."

Dr. Gada:
Right.

Dr. Iyer:
"Put yourself or your loved one and say, 'What do I want for myself in that circumstance?' And if the answer is that 'I don't want the debris in the brain,' it's a no-brainer. It's the same answer for everybody else. You don't want to put anybody else at risk."

Dr. Gada:
Excellent. Yeah, I think that about caps it up. Thank you for your time.

Dr. Iyer:
Thank you.

Dr. Gada:
I think this has been a great conversation. We've uncovered a lot. So, I wanted to close this segment of the Structural Heart to Heart podcast. I'm Hemal Gada. Vijay Iyer, thank you very much.

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