Robert J. Applegate, MD

Dr. Applegate discusses recent CMS designation of the field, as well as access routes, technology, and other important TAVR considerations.

What are your thoughts on the Centers for Medicare & Medicaid Services (CMS) recently granting specialty designation for interventional cardiology?

I think it's a great step for the field of interventional cardiology and our patients. Specialty designation means CMS recognizes that the therapies and services we offer differ substantially from those of other specialists. Moreover, specialty designation provides direct access for interventional cardiologists to CMS regarding issues relevant to care and delivery of our services, which ensures that we have a voice when it comes to issues of quality for patient care. As we enter into an era of value-based care, this designation will allow active and direct dialogue with CMS about fair and balanced processes concerning quality and resource utilization. On a practical level, interventionists may now be able to submit a charge for a consultation from a general cardiologist, if it is appropriate under the patient's insurance plan.

As the complication rates for transcatheter aortic valve replacement (TAVR) have begun to decrease, what are the goals of future device iterations?

Now that this life-saving procedure has been generalized to most tertiary centers in this country, the focus going forward will be on optimal patient selection and reducing complications. Technology, specifically smaller-diameter catheter platforms, will play a huge role in minimizing the vascular-related complications associated with TAVR. Whether technology in the form of embolic prevention devices can reduce the incidence of stroke remains to be determined. We can only be hopeful that they will.

According to recent data from the UK TAVI registry, more transfemorally treated patients were alive at 3 years than patients treated via a nontransfemoral procedure. Is this because the access route itself is better suited for this procedure or perhaps because the femoral arteries/anatomy were viable and hence the patients were somewhat healthier?

I think it's a combination of both factors. The transfemoral approach itself is less invasive, and as you have alluded to, patients requiring a nontransfemoral approach often have extensive vascular disease and other significant comorbidities that contribute to worse outcomes.

Which access route might you theorize will become the preferred approach for TAVR? Will it remain transfemoral and transapical, or do you believe that subclavian or direct aortic access might provide unique advantages?

The transfemoral approach will always be the preferred approach in my opinion, particularly as we see a continued decrease in the diameter of the catheter platforms. The subclavian route would be my next choice, as long as the patient does not have an internal mammary artery graft to a coronary artery on the same side as the sheath. The choice between transapical and transaortic will likely continue to be individualized by the surgeons, with some surgeons simply preferring one over the other. In some cases, anatomy may dictate one approach over the other; for example, in the case of a left internal mammary artery graft to the distal left anterior descending artery, it may be preferable to use the transaortic approach.

As the surgical risk threshold decreases for TAVR candidates, it reasons that patient age will also become younger. Do you have any concerns about device durability and the potential need for valve-in-valve or valve-in-valve-in-valve procedures in these patients with longer life expectancies?

The issue of valve durability remains an important issue concerning the long-term role of TAVR in the treatment of severe aortic stenosis. Assessing the long-term durability of TAVR has been more challenging than for surgically treated patients because TAVR started in extreme-risk patients, who, in general, were much older than the surgically treated patients. Thus, data on durability and outcomes have been somewhat limited, as many of these patients died before problems with

(Continued on page 89)

(Continued from page 90)

durability potentially surfaced. Although having said that, there does not appear to be a signal of a durability issue with the information we currently have.

The question of valve-in-valve is interesting with regard to influencing the selection of the initial valve type. There is an emerging concept that TAVR may actually allow the use of a bioprosthetic valve in younger patients who are treated surgically (avoiding the need for anticoagulation for a mechanical prosthesis), because a mechanical device could be placed as the second valve, should that be necessary. Time will tell if this becomes an accepted and satisfactory strategy.

Pharmacology is also an important topic on the minds of TAVR physicians. What is your standard protocol for type of drug and duration? Does this change if the patients has/develops atrial fibrillation?

The decision to use dual-antiplatelet therapy (DAPT) after TAVR is influenced by several factors. We recommend 3 months of therapy, per the guidelines, and typically recommend clopidogrel as the P2Y12 inhibitor. If there are high-risk features of bleeding, or there has been recent bleeding, we will review the need for DAPT after 1 month of treatment. If the patient also requires anticoagulation (ie, for atrial fibrillation), we lean toward the use of aspirin alone with the anticoagulant.

Do you have a bridge protocol for those on DAPT before TAVR? Is this the same or similar to what you would do prior to drug-eluting stent implantation?

We usually do not interrupt DAPT if we plan a transfemoral approach. If a transapical or direct aortic approach is planned, we will stop the P2Y12 inhibitor 5 days before the procedure and continue aspirin. The P2Y12 inhibitor is restarted on day 1 or 2 after TAVR, depending on the patient's clinical status and evidence of any ongoing bleeding from the surgical access sites.

What new technologies have you recently integrated into your cath lab, and how do you train the staff? What are the challenges, and how do you decide what to add?

Our most recent new technology introduced into the cath lab has been the MitraClip device (Abbott Vascular). The decision to add this service to the lab was to provide more comprehensive solutions to valvular disease treatment for our patients, as well as to complement our TAVR program. Extensive didactic and technical training is provided on-site by the vendor for the staff.

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What benefits have you experienced when treating patients in the outpatient setting (the Outpatient Clinic of Davie Medical Center) as opposed to the typical hospital setting? What is the threshold for choosing outpatient versus inpatient treatment?

Most of the country, and world, have been transitioning from an inpatient to an outpatient model of procedural services and care. Although there are certain advantages for the patients (easier access, family oriented care, etc.), this transition has been heavily influenced by cost concerns. As CMS and other payors have reduced or eliminated payment for inpatient services, the less financially rewarding ambulatory payment classification codes have forced a substantial rethinking of aligning payments with costs. Outpatient and same-day settings lend themselves best to a lower-cost model of care delivery. Most centers rely on guidelines to establish appropriate patient characteristics and procedures for outpatient procedures, which helps ensure that optimal safety is maintained to the fullest extent possible. ■

Robert J. Applegate, MD, is with the Section of Cardiology, Wake Forest School of Medicine in Winston-Salem, North Carolina. He has disclosed that he is on advisory boards for Abbott Vascular and The Medicines Company. Dr. Applegate may be reached at (336) 716-2718; bapplega@wakehealth.edu.