AN INTERVIEW WITH...

Ron Waksman, MD

Dr. Waksman discusses using intravascular ultrasound guidance for drug-eluting stent implantation, enhancing patient outcomes and quality of life in structural heart therapy, and more.

Do you tailor the choice of vessel access for percutaneous coronary intervention (PCI) to each individual patient? Which patient-specific factors should be considered when making this choice?

The choice of vessel access should be individualized across all patient factors, including patient age, vessel tortuously, peripheral artery disease, patient body mass index, anticoagulation regimen, the complexity of the procedure, and proficiency of the operator in performing radial or femoral intervention. We are moving toward individualized medicine, which includes the choice of access and the understanding that one size does not fit all. The data support fewer bleeding complications with a radial artery approach, but access is not standard and should take all factors into consideration to determine what is best for the patient in terms of access of choice.

Why do you think intravascular ultrasound (IVUS) guidance for drug-eluting stent (DES) implantation has been shown to reduce revascularization rates? Should IVUS be used more widely for this procedure?

The use of IVUS enables us to better understand the morphology of the vessel and allows us to assess the outcome of the PCI procedure after stent implantation. Many times, we are relying solely on angiography, which does not provide sufficient information. Angiography alone does not tell us if the stent is well expanded or well apposed, if the entire lesion is covered, etc., but by adding a real-time invasive imaging tool like IVUS or optical coherence tomography, we are able to offer better results. These improved results will in turn translate to fewer recurrent events over time, which has been shown in many studies. Although many times we believe we can perform PCI without IVUS, we might be surprised at the amount of information IVUS can offer. Routine use of IVUS can potentially reduce subacute and late events.

What is the latest on the detection of vulnerable plaque for preventing cardiac events? Other than assessing individual plaques, are there other specific patient risk factors that must also be taken into account?

First, we have to differentiate between the vulnerable patient and vulnerable plaque. Vulnerable patients are those who are at high risk to experience an event, and in those patients, we more or less know the risk factors, such as hypertension, diabetes, dyslipidemia, and previous relevant history (eg, smoking or family history of coronary artery disease). With respect to vulnerable plaque, an ongoing debate for the past 20 years has been whether we have the imaging modality to detect vulnerable plaque, and once we identify it, can we prevent an event from occurring?

I am currently the principal investigator of the largest trial ever conducted to detect vulnerable plaque based on new infrared technology, which scans the artery for the total lipid content. We are enrolling patients and imaging their coronary arteries with a lipid scan to see if those findings are correlated to future clinical events. Other trials are testing the use of bioresorbable scaffolds to prevent future events by targeting the identified high lipid containing plaques.

Generally, once a vulnerable plaque is detected, we can decide whether to treat it locally with a stent or a scaffold. We should also think about treating it with systemic medication that could affect all plaques in the body. Intensive lipid therapy with a high dose of statins or PCSK9 inhibitors may alter the composition and the vulnerability of these plaques. The ultimate goal is finding a therapy that will stabilize these plaques and prevent them from causing a future event.

If patients 65 years and older are less likely to receive a DES, what treatment is used instead and why?

In the past, elderly patients were treated with bare-metal stents, but I believe that the days of bare-metal stenting are over—every patient should be treated with either a DES or bioresorbable scaffold. These devices will provide better outcomes, and there shouldn't be any age discrimination in terms of which type of stent we choose for our patients. The key issue in the elderly population is to optimize the vessel preparation prior to stent or scaffold placement in order to achieve full expansion of the stent.

What is the best way to discover myocardial injury and reduce the amount of damage done?

Myocardial injury is best assessed by the use of noninvasive imaging (ie, magnetic resonance imaging or positron emission tomography). In terms of reducing the affect of

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this type of event, there are two components involved. One is to open blockages as quickly as we can, which enables oxygenation and blood flow to the regions at risk. Two, which is more complicated, is to minimize microvascular damage, distal embolization, and reperfusion injury. Although significant progress has been made with quickly opening vessels and reducing the door-to-balloon times, there is an unmet need in finding the "magic bullet" to minimize these complications. Thrombus aspiration, filters, cooling, nitroprusside, adenosine, and other modalities have had mixed results, but the research on minimizing myocardial injury has not yielded a satisfactory solution. Patient education of the signs and symptoms of myocardial infarction is key to reducing symptom onset to balloon time, and therefore a reduction in myocardial injury.

Is there a possibility of making monitored anesthesia care the default strategy over general anesthesia for TAVR? What would it take to make this the clear first option?

In terms of transcatheter aortic valve replacement (TAVR), one way to enable more monitored anesthesia is to have the cooperation of the anesthesiologist. Second, we should minimize the use of transesophageal echocardiography, which patients usually do not tolerate well and drives the need for general anesthesia.

Nevertheless, some patients, especially those who are unstable hemodynamically, do better under general anesthesia. The goal is to make the procedures less invasive and simple. Monitored anesthesia is feasible and safe in most patients and should be the default, if feasible.

What is your current outlook on the use of TAVR in the low-risk population?

The use of TAVR for patients with severe aortic stenosis has continued to expand from the extreme- and high-risk patients to the intermediate-risk patients, soon to be approved for marketing in the United States, and further to the low-risk populations currently under study protocols. We have to admit that there is a gray zone between intermediate- and low-risk patients. The data from the randomized clinical trials of TAVR versus surgical aortic valve replacement (SAVR) for the intermediate population are encouraging. Noninferiority results support the percutaneous approach, whether this will expand to the low-risk population remains in question. Another critical question related to TAVR is the durability of the percutaneous valves, especially in the younger population. Patients' choice, in general, is to have less-invasive procedures with early ambulation, but without compromising outcome. If we follow the pattern that we have seen with high- and intermediate-risk cohorts, there is a reason to believe that these findings would be the same in low-risk patients, and so we would see at least equivalent outcomes between TAVR and surgery. If that proves to be the case, TAVR would also be the desired procedure for the low-risk patient. Younger patients will likely require valve durability for 15 years or more, and they may still need another procedure down the road. So although I think the emphasis on low-risk TAVR should be centered around the acute outcome, we should also consider the long-term plan for this population.

Currently, we have three trials looking specifically to the low-risk populations, two are randomized to SAVR, and our trial is a registry matching the patient population to low-risk patients who were treated with SAVR from the Society of Thoracic Surgeons database.

Which type of next-generation structural heart therapy do you think holds the most promise for enhancing patient outcomes and quality of life?

I'm glad that you asked me about the quality of life, because for the elderly, this is the main consideration. We anticipate a partial approval to treat patients with patent foramen ovale (PFO) who have had a stroke for secondary prevention. The left atrial closure devices can free patients with atrial fibrillation from chronic anticoagulation therapy and at high risk for bleeding. We are also in the beginning of understanding the challenges with percutaneous devices for mitral disease, primarily for mitral and tricuspid regurgitation, and if surgery can be substituted with less-invasive procedures, that would hold a lot of promise to improve patients' quality of life. There is still hope that we will figure out the potential role of renal denervation to control blood pressure. We are still seeking mechanical solutions to treat patients with advanced heart failure and minimize myocardial injury for patients undergoing myocardial infarction. No doubt, it is an exciting time to be engaged in research and device development for structural heart disease. ■

Ron Waksman, MD
Director
Cardiovascular Research and Advanced Education
MedStar Heart & Vascular Institute
Professor of Medicine, Cardiology
Georgetown University
Washington, DC
Ron.Waksman@Medstar.net
Disclosures: Consultant to Abbott Vascular, Biotronik, Biosensors, Boston Scientific Corporation, Medtronic, Astra Zeneka, and Med Alliance.