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Endeavors of the Heart: Leveraging Innovative Technologies for Transcatheter Therapies

Narrator:

Welcome to Medical Breakthroughs from Penn Medicine, Advancing Medicine Through Precision Diagnostics and Novel Therapy.

Dr. Birnholz:

Although it is one of the newer developments to enter the cardiology space, transcatheter aortic valve replacement or TAVR procedures have already risen in popularity over the course of just a few years. With the concept of TAVR proving successful, there has been a dramatic increase in new technologies within the industry. How will this impact cardiovascular care across the broader therapeutic landscape going forward? This and other questions will be the focus of today's episode of Medical Breakthroughs from Penn Medicine on ReachMD. I am Dr. Matt Birnholz and joining me is Dr. Howard Herrmann, Health System Director for Interventional Cardiology at Penn Medicine. Dr. Herrmann, thanks for joining us.

Dr. Herrmann:

Thank you very much. It is a pleasure to be here.

Dr. Birnholz:

Great to have you. Just to start off, can you share some of the clinical background and research interests that led to your current work today?

Dr. Herrmann:

Sure. I have been interested in the catheter-based approach to valvular heart disease ever since I started my career and my training more than 30 years ago. At that point, the only therapy we really had was the use of a balloon to open up a stenotic or stuck heart valve. We utilized that for patients who had rheumatic mitral stenosis and for some forms of aortic stenosis. The last 15 or 20 years we have seen this explosion in new technologies that allow for the transcatheter treatment of both aortic stenosis as you already mentioned and now, I think, the next field of endeavor is going to be the world of mitral regurgitation.

Dr. Birnholz:

Really interesting. Thanks for sharing that background with us. Just to level set on how we have gotten to this current point with transcatheter therapies, what was the treatment experience like for you and the outlook for your patients before TAVR? I am thinking, for instance, of open-heart surgery when that was really the only option.

Dr. Herrmann:

That is true. As I mentioned, we did try the use of a balloon, just a straightforward balloon similar to what we use for angioplasty but a bigger version in calcific aortic stenosis back in about 1987 or 1988. We found relatively quickly that that did not work, that just blowing up a balloon gave some transient improvement to the stenotic aortic valve, but it restenosed very quickly within less than a year. The field basically stayed still until about 2002 when Professor Alain Cribier in France tried putting a valve that was sewn inside a stent on a balloon and inserting that in the aortic valve. He demonstrated the feasibility of doing that in a patient who had no other options back in 2002 who could not have open-heart surgery, which is the traditional approach to this, where we do a sternotomy or a mini-sternotomy, open up the aorta, cut out the calcific aortic valve, and sew in a new one. This was a catheter-based option. It could be done on a conscious patient, and it worked surprisingly well in that patient.

That really ushered in this whole era. We did the first transcatheter aortic valve replacement at the University of Pennsylvania in late 2007. That is when it sort of began in the U.S. as an investigational procedure. Over the last 10-12 years, we have gradually marched

down the risk profile of patients. First, we tried it in patients who had no other option. They could not have open-heart surgery. It was found that it was clearly better than doing nothing. Then we moved into the high-risk population, then the intermediate-risk population, and most recently with the recent presentation of two large trials at the recent American College of Cardiology meeting, it was demonstrated that it is as good, if not better, than open-heart surgery even for low-risk patients. Essentially, anybody with aortic stenosis is now a candidate for TAVR.

Dr. Birnholz:

That is fascinating. Just to understand, the first TAVR procedure being performed at your institution. That is quite a background to be able to move in on proving that this is a really successful new player in the field. Were there any roadblocks or obstacles that you and your colleagues came across throughout that evolution over the last several years?

Dr. Herrmann:

Sure. The development of this procedure has really evolved greatly. We are essentially on third and fourth generation devices. The initial devices were very large and most of the time required us to do a surgical cut-down on the femoral artery in order to get into the artery with these devices because they were so big. We were doing them all under general anesthesia, utilizing transesophageal echocardiography to help guide the positioning and the sizing of the devices. Over that evolution, we now have smaller devices that are easier to place, and we have evolved from a procedure that was done only under general anesthesia and required five to seven days in the hospital to a procedure that we do now all percutaneously under conscious sedation while the patient is sedated but still awake, not on a ventilator. We do not routinely utilize transesophageal echocardiography, and most of our patients are going home in just a day or two and resuming their normal lives.

Dr. Birnholz:

For those just tuning in, this is Medical Breakthroughs from Penn Medicine on ReachMD. I am Dr. Matt Birnholz, and I am speaking with Dr. Howard Herrmann from Penn Medicine on the latest advancements in cardiovascular transcatheter therapies, such as TAVR. Dr. Herrmann, I want to come back to some of the work that you and your colleagues are doing to innovate this field, to improve the safety and efficacy of TAVR. You have walked us through some of the work that has been done to get through some of these obstacles to make it a much safer, faster, and more affordable procedure. What is the latest from your vantage point now that is going on at Penn?

Dr. Herrmann:

From the standpoint of TAVR, this has really become the procedure of choice for the majority of patients now with aortic stenosis. In the early days of this procedure, we were trying to figure out who should be a candidate for TAVR, and now TAVR has become the default, and we are trying to figure out who should be a candidate for surgery, if anyone. There are still some candidates for surgery where it may be better, but we are gradually moving into this as the default strategy where the majority of patients with aortic stenosis will be offered TAVR. We are treating younger patients, even some patients with bicuspid aortic valves. That is still investigational. We are utilizing devices to help prevent stroke. We are minimizing the leaks that occur, minimizing the need for pacemakers afterwards, and it is really becoming a mainstay default strategy for the great majority of patients who have aortic stenosis.

Leveraging that, we began to use this and other technologies on the other valves, so we have learned that we can put TAVR valves in old surgical prostheses that are now failing either in the aortic position or the mitral position. We are gradually moving into new devices for treatment of mitral regurgitation, things like MitraClip, which we have been doing for a number of years, but now there are lots of new devices coming, including transcatheter mitral valve replacement procedures that are leveraging some of the experience we have learned from TAVR.

Dr. Birnholz:

On that subject of mitral regurgitation and the investigations there, what is currently being investigated from you at Penn and among your colleagues to help update and innovate on the technologies that are available for patients?

Dr. Herrmann:

The major approved device for treating mitral regurgitation in the U.S. is the MitraClip. This is a little more complicated than just a clip. It is a device that functions like a clip and allows us to put together the anterior and posterior leaflets in their midportions to create a dual-orifice valve. That technology has been around since about 2003. In fact, we, at Penn, did the second case in the U.S. at that time and have remained one of the leading sites for doing MitraClip procedures. It is now approved for patients who are at high risk for surgery who have primary mitral regurgitation. Recent data in a trial that we were part of called COAPT demonstrated that it also works quite well in patients who have secondary MR. These are patients who have heart failure and mitral regurgitation, a much larger population of patients. We have been seeing an increase in the use of MitraClip for those patients pending what we anticipate will be a relatively soon reimbursement decision by CMS. It is already FDA approved for that population.

There are a number of investigational approaches that we are also part of for the patients who are not good candidates for MitraClip. We

are part of the Cardioband trial, which is a ring that can be placed percutaneously to do an anuloplasty, similar to what the surgeons do. We have a device that also allows us to do some cinching of the ventricle just below the mitral annulus with a device that also reduces mitral regurgitation. Then there are several trials going on in the U.S. for transcatheter mitral valve replacement, true valves that are put in and dedicated valves for the mitral position. We are part of the early U.S. feasibility trial utilizing the EVOQUE transcatheter mitral valve replacement and have done more of those than any other institution in the U.S.

I think the options that are going to be available for patients with mitral regurgitation are going to be increasing. We still have to prove which ones are best and for which patients. It is a more complicated disease than aortic stenosis, but I think the hope is that over the next five or ten years, we will reproduce the success of TAVR in the mitral position and even in the tricuspid position where we are starting to do it as well.

Dr. Birnholz:

That is excellent, and it speaks to remarkable momentum being carried forward for patients with mitral regurgitation. Let me swing back for a moment to aortic stenosis. Since we are on the subject of trials, there were recent studies that came out and were discussed at ACC, including PARTNER 3, EVOLUT, I believe, that are speaking to perhaps expanding the eligibility criteria for TAVR. You mentioned it is already a default and becoming fast a default for these patients. What studies have come out both in the recent past and perhaps are projected to come out in the future in these research efforts for TAVR?

Dr. Herrmann:

These two were very important trials in that regard, both of which demonstrated that in low-risk patients the PARTNER 3 trial showed that the TAVR with the balloon expandable device was superior to surgery. We had fewer deaths, fewer strokes, and fewer rehospitalizations at both 30 days and one year, reaching superiority at one year over surgery. Similarly, the EVOLUT trial was designed a little differently. It had an endpoint that only included death and stroke, but it also showed noninferiority to surgery with endpoints that were actually slightly lower than surgery, although not statistically different. I think both of these trials, which have not yet been published but have been presented - - they were actually published online - - they have not been published in print yet, demonstrated that we are going to move into this low-risk population pretty aggressively once there is FDA and CMS approval for it in that population. Currently in the U.S., somewhere around 50% to 55% of all patients with aortic stenosis are getting TAVR. This could easily bring that number to 70% or 80% of all patients with aortic stenosis. There is going to be a rapid expansion for these patients.

There are still some unknowns in this space. We know that patients who get TAVR do have a little bit more leakage around the outside of the valve than surgical valves that are sewn in, and whether these mild leaks over time are an issue for patients remains unknown. We are going to be following the patients in these trials for ten years in order to understand that better. Then there is the whole issue of durability. We do not know that TAVR valves are any less durable than surgical valves, but we do not have the same degree of followup for these patients that surgical valves have had over decades. There is that concern that maybe these valves will be a little less durable and that for a younger patient that may be an issue. At this point, I do not think we have any evidence that that is the case.

Dr. Birnholz:

Dr. Herrmann, before we wrap up, I do want to stay on this theme of exploring the unknowns. Let me get your thoughts on what you think is ahead of us, looking further down the road, for transcatheter therapies beyond perhaps even mitral regurgitation and all the work that is being done at Penn there. Is there anything that you are particularly excited about in the near or long term?

Dr. Herrmann:

I think mitral regurgitation is a big issue because it is a more common problem, and if we had really good solutions for that, I think that will really change the landscape of the ability to treat patients. The other thing that I think is coming is going to be the use of these devices in concert. Many patients have more than one valve problem. It is not uncommon for a patient with mitral regurgitation to also have tricuspid regurgitation due to the flows going backwards into the pulmonary circulation, raising the pulmonary artery pressure, and that can lead to tricuspid regurgitation. There are patients who have aortic stenosis and mitral regurgitation. I think the ability to start to combine some of these therapies and really treat the entire patient from coronary disease with PCI to multiple valve lesions with different devices and really avoid open-heart surgery altogether for a significant number of people is really going to be a big advance going forward.

Dr. Birnholz:

With that great thought of treating the whole patient in mind and looking at what is next on the horizon to help us get there, I really want to thank Dr. Howard Herrmann for sharing his insights on transcatheter therapies in cardiovascular care. Dr. Herrmann, it was fantastic having you on the program. Thanks so much.

Dr. Herrmann:

Thank you.

Narrator:

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