BroadcastMed | Grand Rounds: Melody Valve Therapy Overview: Transcatheter Pulmonary Valve and Tricuspid/Mitral Valve-in-Valve

ALLISON CABALKA: Hello. I'm Allison Cabalka, associate professor of pediatrics and a consultant in the division of pediatric cardiology at Mayo Rochester. I'd like to review Melody valve therapy, including percutaneous pulmonary valve therapy and tricuspid and mitral valve-in-valve therapy using the Melody valve.

I would like to acknowledge my partners, Drs. Cetta, Hagler, Rihal, and Taggart, who have been instrumental in the development of our Structural Heart Disease Program here at Mayo Rochester. I do have a disclosure in that we are participating in the Medtronic post-approval study involving the Melody valve in the pulmonary position. We are currently enrolling patients and gathering data on the function of the valve in a real-world setting.

The objectives of the presentation today are to review lesions that may benefit from percutaneous pulmonary valve therapy, to review the acute and intermediate-term results utilizing the Melody valve in the pulmonary position, and to briefly discuss valve-in-valve therapy for failing bioprosthetic mitral and tricuspid valves.

So we first ask ourselves why we would use a percutaneous pulmonary valve. While normal right ventricular outflow tract conduits that are placed surgically will eventually fail, that may take place over years. But it may be even more rapid than that.

There are hazards of multiple open-heart surgery procedures in our patients with complex congenital heart disease, some involving multiple-redo median sternotomies-- perhaps even as many as four or five redo median sternotomies as we see them for treatment. Percutaneous pulmonary valve therapy extends the life of existing right ventricular outflow track conduits and avoids the need for repeat surgical procedures.

In this slide, we see the bovine contegra three-leaflet valve mounted inside its NuMed platinum/iridium stent platform. This valve functions, essentially, as a normal bioprosthetic tissue valve and is approved for humanitarian device exemption use in the United States. There is a post-approval study under way as I mentioned.

Current indications for Melody percutaneous pulmonary valve therapy involve treatment of a dysfunctional circumferential right ventricular outflow tract conduit. That is a conduit that was greater than 16 millimeters diameter at the time of implant and has an inner diameter of less than 22 millimeters at the time of valve therapy.

Conduit failure occurs by many mechanisms, and the indications for a valve replacement in this setting involve more than moderate pulmonary valve regurgitation and treatment of pulmonary valve stenosis with a mean RV-PA gradient of over 35 millimeters of mercury by echo or peak-to-peak cath gradient of the same.

Let's discuss a case briefly before we move into reviewing some of the results. This is a 49-year-old gentleman who was originally treated with the Ross procedure in 1997 for aortic regurgitation due to bicuspid aortic valve disease. At that time, he had a 24-millimeter homograft placed from the right ventricle to the pulmonary artery as part of that Ross procedure.

He had an ascending aortic aneurysm repair in 2006 but then had Corynebacterium endocarditis in 2009. This essentially destroyed his pulmonary homograft so that he was left with severe pulmonary valve regurgitation due to flail-leaflet and pulmonary stenosis due to residual vegetation tissue.

He was cleared from an infectious disease standpoint and referred to us for Melody valve therapy. Thankfully, his aortic valve was completely spared, so percutaneous options were available. In this echocardiogram showing the appearance of his right ventricular outflow tract homograft before therapy was undertaken, we can see flail leaflets with thickened appearance and severe pulmonary valve regurgitation.

If we look at an overview of the procedure, each patient will have a venous sheath and an arterial sheath and undergo prograde right and retrograde left heart catheterization. This is generally performed under general anesthesia.

And right ventricular outflow tract angiography outlines the anatomy of the existing conduit so that it can be evaluated very carefully. Aortic root angiography and sometimes selective coronary angiography will be utilized as needed to clear the coronary arteries from potential compression due to the therapy in the right ventricular outflow tract.

During implantation in a pulmonary homograft in a patient following a Ross procedure, it is imperative that we clear coronary anatomy in detail. So our patient has a 22-millimeter, high-pressure Atlas balloon inflated in the right ventricular outflow tract to simulate the anatomy of the outflow tract after implantation of the Melody valve. And selective left coronary angiography confirms that there is no compression of the coronary during that implant.

So when we think about the right ventricular outflow tract anatomy in terms of preparing the landing zone for Melody valve implantation, it's important in certain settings to pre-stent the existing outflow tract. This is not necessary in the presence of a bioprosthetic valve, but when there is a homograft, it's very important.

In the left-hand panel, we see an angiogram prior to preparation of the landing zone and following balloon dilation. The catheter is positioned across the wire in the main pulmonary artery. An injection shows the narrowing of the homograft and severe pulmonary valve regurgitation.

If we look at the right-hand panel, we can see a stent being placed in this existing homograft to prepare the landing zone for the Melody valve. And this is placed on a 22-millimeter balloon so as to simulate the size at which the Melody valve will be implanted.

Once our landing zone is prepared with stent implantation, the Melody valve will be advanced on its ensemble system into the right ventricular outflow tract. This is a 22-French system through the right femoral vein, and the balloon size is 22 millimeters also. There is an inner balloon that can allow for adjustment of the Melody valve as we are placing it. And then once the outer balloon is inflated, the Melody valve is delivered securely within that existing landing zone stent or within the existing bioprosthetic valve.

Following implantation, angiography is performed, which shows no evidence of significant pulmonary valve insufficiency and a very nice appearance of the right ventricular outflow tract with appropriate position of the Melody valve within the existing stent.

Intracardiac echo is often used for evaluation of the Melody valve in these situations, where the probe will be advanced into the right ventricular outflow tract. And we are imaging directly below the newly implanted Melody valve. On the left-hand panel, we can see nice mobility of the thin leaflets within the stent. And on the right-hand panel-- laminar color flow with trivial pulmonary valve regurgitation.

Patients are monitored overnight and typically dismissed the following day with instructions to take aspirin for six months and observe infective endocarditis prophylaxis for a lifetime.

To review briefly safety considerations with respect to the Melody valve-- We have procedural risk. And primarily, that will involve coronary artery compression, especially in the setting where the patient has had manipulation or surgical translocation of the coronary arteries, such as post-operative arterial switch procedure or the Ross procedure. So with this, we will take care to perform pre-balloon dilation in the outflow tract prior to stent implantation with simultaneous coronary angiography.

Conduit rupture can occur, particularly with smaller, calcified homografts. So we have to be very careful with the balloons sizing, and that may be with serial increasing balloon-size dilations and the availability of alternative covered stents in case of conduit rupture.

The Melody valve itself is considered a covered stent. It may not be as long as some other versions that are available, so we're very careful, especially in the setting of a homograft. Device embolization is extremely rare in this situation.

As far as device risk, one of the longer-term risks would be valve failure. And we'll discuss that in a moment. Stent fracture can occur, particularly in patients who have a retro sternal conduit position with compression between the aorta and the sternum. In this setting, if there is a homograft, multiple pre-stents will be necessary. If it is a bioprosthetic valve, then typically, the rigid surgical ring will support the Melody valve without risk of compression.

Pulmonary embolism is possible but not reported following valve implantation. And endocarditis risk is present as it is in any bioprosthetic or mechanical valve.

If we look at the results of the investigational device study in the United States, we see in the left-hand panel of this graft-- pre-implantation, the majority of patients had more than moderate or severe pulmonary regurgitation. And in follow-up, all of them had significant freedom from recurrence of pulmonary valve regurgitation with mild or less in all patients in which the valves were intact.

Valve failure is very uncommon. And the mean right ventricular outflow tract gradients fell immediately at the time of the procedure following Melody implantation. And this is holding true at the follow-up evaluations.

So time will tell as we obtain longer-term follow-up what the comparison will be in terms of Melody valve performance and surgical bioprosthetic valves.

Let's shift a moment to discuss Melody valve-in-valve therapy before we conclude our discussion. The goal of valve-in-valve therapy is to replace an existing bioprosthetic valve with a new tissue valve and avoiding the need for open-heart surgery. So this is an adjunct to surgery in patients, obviously, who have already had a valve replacement.

This is a patient who has Ebstein anomaly. In the left-hand angiogram, we see a pre-procedure angiogram with the catheter positioned in the right ventricle. Injection there shows severe tricuspid valve regurgitation. And in addition, this patient had moderate-to-severe tricuspid valve stenosis.

In the right-hand panel, after the Melody valve is placed within the existing bioprosthetic valve, we see resolution of the tricuspid regurgitation. And the gradient is abolished by echo-Doppler assessment.

We published our experience with transvenous, antegrade Melody valve implantation in both tricuspid and mitral bioprosthetic dysfunctional valves in 2013. This was a case series in children and adults, and we reviewed our experience with the first 19 patients in whom we performed this procedure. All patients had failing bioprosthetic valves, not native valves, and certainly not mechanical valves.

The valve sizes were quite a wide range, and we were able to implant this Melody system even into a valve as large as 33-millimeter sewing ring size. And due to stenosis of the leaflets, it is possible to implant the Melody into larger bioprosthetic valves.

There is a relatively high-risk STS score for the mitral patients-- 13.3%-- and a tricuspid patient group of 10 patients that we were able to implant valves into successfully-- a wide range of ages from 10 years to 88 years. And we were able to do this with a transvenous approach in all 19 patients successfully.

There were no valve embolizations, and bleeding complications occurred in four patients related to the apical approach for these mitral valve procedures.

Our total experience now numbers just over 35 patients and is growing. And we are gathering more medium-term follow-up data with respect to this experience of the Melody valve also.

This is a 3D echo showing a bioprosthetic valve-- a mitral valve-- looking from the left atrium down through the valve leaflets. And you can see that this valve is very stenotic. So this is a valve into which we can successfully place a Melody valve percutaneously for more definitive, catheter-based therapy rather than having a high-risk, senescent, frail patient undergo surgical intervention.

In this panel in the upper left, we see the valve prior to implantation. In the middle panel, the B panel, we see the transseptal approach with a wire passed through the valve. This will be snared through a small sheath that's placed in the apex of the ventricle percutaneously. And this sheath is exteriorized-- or the wire is exteriorized-- as we see in panel C. This will be secured for obtaining the venous transseptal transvalvular apical rail to place the Melody valve successfully in the mitral position.

So the ensemble delivery system is drawn across the valve. The valve is exposed and delivered within the existing bioprosthetic valve as we can see in panel F. What that looks like following successful valve delivery is we now have normal leaflet motion. We have a valve inside the bioprosthetic ring that is normally positioned.

And on transesophageal echo evaluation on the left panel, we see very nice leaflet motion, normal position of the stented mitral Melody within the existing bioprosthetic valve. And in the right-hand panel with color Doppler, we see laminar flow, no evidence of stenosis, and only trace regurgitation.

The basic approach for tricuspid is slightly different in that we do not exteriorize a valve rail, but the wire is positioned deeply in the pulmonary artery branch. This can be done either via femoral approach or internal jugular approach. We will balloon interrogate the tricuspid valve routinely since these tend to be larger bioprosthetic valves, and often, more regurgitation is present.

If we are assured that the valve profile is less than 22 millimeters, we are safe to proceed with a 22-French, 22-millimeter ensemble system for placement of the Melody. And in the right-hand panel, you can see the outer balloon being inflated to deliver the Melody within the existing tricuspid bioprosthesis.

So in our overall early results, we see improvement in NYHA class functional status. Many patients-- moving out of class 3 to 4 into class 1 to 2. And we see, certainly, a significant improvement in the gradients in these valves, which were in the majority of situations quite stenotic to begin with.

We have had only one hyperacute tricuspid valve failure. This patient had surgery for this and had early failure of the homograft tissue valve that was placed in the same position. And there were three deaths in our mitral group related to patient status, frailty, and senescence in the very elderly population.

So in conclusion, transcatheter pulmonary valve therapy is a safe and effective option for patients with failing right ventricular outflow tract conduits in many of our congenital heart patients who have undergone surgical repair of tetralogy of Fallot, the Ross procedure, post-operative Rastelli, or repair of pulmonary atresia VSD.

This is very good therapy to avoid multiple repeat median sternotomies. It is certainly an adjunct to surgical therapy, and multidisciplinary evaluation with the surgeon, cardiologist, and the structural heart disease team is necessary for pre-catheterization assessment of these patients.

Proper patient selection requires recognition of high-risk coronary anatomy and high-risk conduit anatomy. And early Melody valve failure is very uncommon, and ongoing data is being assessed. We hope that the valve will function just as well as surgically placed bioprosthetic valves-- again, allowing a very nice part of the therapy in terms of approaching these patients without the need for multiple repeat median sternotomy operations.

The newer technology and application of this to mitral and tricuspid valve-in-valve therapy for treatment of failing bioprosthetic valves is unique and developing also. And I think medium- and longer-term follow-up will show us how these valves function in a ventricular setting in terms of systemic ventricle in some patients and in the right side in other patients, perhaps with pulmonary hypertension.

So in conclusion, transcatheter therapy is an exciting part of the treatment of congenital heart disease and structural heart disease in this day and age. Thank you for your attention.