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PEDIATRIC TRANSCATHETER PULMONARY VALVE (TPV) IMPLANTATION
CHILDREN'S HOSPITAL BOSTON
BOSTON, MASSACHUSETTS
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00:00:12
ANNOUNCER: Over the next hour, live from Children's Hospital Boston's cath lab, see cardiologists implant a transcatheter pulmonary valve. This nonsurgical treatment restores effective pulmonary valve function and potentially prolongs the functional life of regurgitant and/or stenotic right ventricle to pulmonary artery conduits. In just moments, the cardiologist's team will present this clinical trial case and answer your email questions. OR-Live makes it easy for you to learn more. Just click on the "request information" button on your webcast screen and open the door to informed medical care. Now let's join the doctors.
00:00:53
PETER LANG, MD: Good morning, everybody. Welcome to the cardiac cath lab at Children's Hospital Boston. We've begun a procedure this morning to implant a pulmonary valve. In the room with me are Dr. James Lock, Dr. Doff McElhinney, Dr. Audrey Marshall, and Dr. Lynn Peng, who are at the catherization table, and Dr. Juan Ibla, who is the anesthesiologist taking care of the patient during the procedure. What we'd like to do is start with Dr. McElhinney, who will give you a bit of information concerning the patient and some background about the procedure that we're in the midst of performing. Doff, can you fill us in on the patient?
00:01:40
DOFF McELHINNEY, MD: Sure. This is a young man in his late 20s with tetralogy of Fallot and pulmonary atresia, which is a form of heart disease in which there is no connection between one of the pumping chambers of the heart, the right ventricle, and the arteries that go to the lungs. He has had multiple surgeries and multiple catheterizations over his lifetime to open up the connection and try to prevent and reduce blockages that develop over time. He has a lot of leakage back from the pulmonary arteries into the right ventricle, which is the pumping chamber, and that is not good for the heart. So the indication to put in a valve here today for him is primarily to get rid of that leakage and help his heart to work better. He's had problems with abnormal rhythms in his heart and really poor exercise capacity as a result of these problems. I want to show a couple of pictures from earlier catheterizations of his. I want to show a picture from 2005, you can see there. This is a picture looking from the side at a couple of stents, which are metal tubes that were put in the connection between his right ventricle and his pulmonary artery. And you can see that down on the bottom part of those they're really flattened out, and that's because these were compressed and broken by the force of the heart beating behind his breastbone. The stent was inside of these, and now we have a picture from a catheterization just over a month ago from 2007, where you see that passageway is a little bit more open. Now, the zigzag, the metal, dark black zigzags, are pieces of the stents that were place before, and the continuous black is a picture with dye that was used to find that pathway, that conduit. Now, this last picture here was from a catheterization a month ago, and we wanted to make sure before we put

in a valve in this patient that he wasn't going to continue to break stents the way that he has in the past. There are currently three in there on this picture from 2005, and now I want to go to a picture on the lateral camera that's live, and this is what his stents look like right now. What you see there are actually four overlapping stents and the darker ones are made of platinum and the less dark are made of steel, but this is staying open pretty well, so we're optimistic that putting in a valve will be okay without having problems without rapid breakage of the stent. Now, this next picture, still on the lateral camera, is another picture. This is an angiogram, which is a picture used to look at the heart and the vessels, and you can see that as the black-colored dye comes out of the catheter, there's a wire, the long, thin structure, that goes out into the lung vessels to help us keep our position there and put the valve in. You can see how this pathway is pretty well opened by the stents that are there at present. We have already today blown up a balloon to try to make the stents that are there a little bit bigger, and also because we have to know exactly how big of a valve to put in, and this balloon, by diameter is about 22 millimeters, which is almost an inch. It's about nine-tenths of an inch, and we expanded that a couple of times, as you can see here, and made it a little bit bigger and decided that we're going to try to use a 22-mm valve. And I'm going to quickly show you here a picture that was taken afterwards, looks more or less the same. And there was one other picture that we've taken so far that I'll show you, and then I want to explain a couple of other things using some slides. So Peter Lang is going to put up a slide that shows the valve that we use. Okay, great. The valve, as you can see here in this slide, is a tissue structure that's sewn inside of a stent, just like the stents that are showing up on these angiogram pictures. And you won't see the actual valve when we put this in, you'll just mainly see the stent, because we're using x-ray images that show metal, and that's what the structure looks like. Now, we took one other picture and I want to show a coronary picture here, Peter, on the slide, right there.
00:06:40
The last picture that we took here-- I'm going to toggle through here, but we're going to go on to the AP camera, please. Okay, good. This is an aortic root picture. This is a picture in the big blood vessel that goes out to the heart and we take this picture in this case primarily to make sure that the blood vessel's going to the heart muscle itself. The coronary arteries aren't too close to the stent and at risk for getting compressed and cutting off blood supply to the heart. And what this picture shows is that basically they're not. In the slide on the other side of the picture there's an example of a balloon being inflated in a conduit and compressing the coronary artery which is being injected. So where we are right now in the case is we have a long sheath and a catheter in the pulmonary artery, the lung artery, through the stent. We are about to put a wire out there, which we use to put the delivery system for the stent into the artery, and there's a slide that Peter's going to show that demonstrates what the delivery system looks like. It's basically a big tube with a balloon and a covering so that we can push the valve up to the place that it needs to go. In this case, that conduit. What I want to show here now, as Dr. Lock is getting in position with the wire and the artery, I want to show the valve in the washing material over here, if you can show me that right here at this table, please. So what we need to do -- because the valve is stored in glutaraldehyde, which is a preservative, we need to wash that off, and we do that by washing it in a series of salt water baths, and each one is more of a rinse, and these are the one, two, and three, and this is the valve here. You wash it for a total of 15 minutes. This is beyond 15 minutes, so I can show you some pictures of the valve as we get ready to put it onto the delivery system. If you can see here, it's probably a little bit far away, but what you're doing is you're looking down the valve from above, and as I scoop this

into the water, okay, you can see here that the valve holds water. We're going to try to bring the camera in a little bit closer to show that and I'll show that to you. But meanwhile, as we go back to the lateral camera, Dr. Lock's in the process of advancing the delivery system. This can be one of the most difficult parts because the heart is very twisty and it can be hard to push a long, sometimes stiff catheter out into the lung vessels. Now, if we can come back to me, I wanted to show you this valve again here. Okay, again, so this is the valve that I've got in my hand here, and if you can see that, we're able to hold water as a valve is intended to do. But if I turn it over and scoop it from the other side, you can see that it opens up completely. I hope that that shows up well. There you can see the blue towel through this. That's what it looks like going out. It opens up completely. And again, showing the backside on the same blue background, the valve looks nice. It has the normal number of leaflets of a valve, which is three, and it holds water, or blood, in the case of the heart. I'm going to leave that in the soak until we finish getting the position for the wires and sheaths that we need, and I'm actually going to go over and help with that. Okay, thank you. All right. Okay. So what we're doing here is this is part of the preparations for putting the correct delivery system and wire out, and this is another balloon that we use sometimes. Sometimes it's difficult to position the catheter exactly where you want it and using a different balloon catheter to help hold your wire in position can be a useful technique.
00:11:52
So while we're doing this, you can see there on the camera, this is what a catheter is for those of you who are not cardiologists. We put the catheters into the body through the big vessels in the leg or in the groin, and then we place what's called a sheath, which is basically a door, a tube that stays in the vessels that allows you to put in different tubes and balloon catheters without losing blood through that opening in the vessel. So that is the structure that helps us to put in different catheters and wires and balloons without losing blood and without doing damage to the blood vessel that we're working through.
Now, I want to show a little bit of information that some of you are already familiar with. And on the slides here -- for those of you in the audience at the talk, you've heard most of this information, but this is the 12th implant that has been done here at Children's Hospital, and currently this device, this valve stent, is only available in the United States on a special trial basis that's approved by the Food and Drug Administration. And it is designed help make sure that medical devices and drugs, in this case medical devices, are safe to put in and leave in humans and do the job that they're supposed to do. And we're nearing the end of that study, and hopefully by some time next year we should have better information on exactly how well it works. In Europe, where it's been used a lot more extensively, the results have been really very good, and in patients with blockage, the valve stent is effective at getting rid of the blockage and also at keeping the valve from developing leakage in patients with leakage, such as this patient today. Its primary role is to prevent leakage, and what the investigators who developed the valve and have used it most extensively have found is that as far out as three years, that the valve works very well in almost all patients with just a little bit of leakage in 10% to 20%.
00:14:36
PETER LANG, MD: Doff, let me answer one of the email questions that's come up. The valve itself is a bovine jugular vein which contains the valve, and it is secured to the stent by a number of sutures. There are continuous suture lines around the proximal and the distal end of the stent-to-valve connection, and then at each node where there is a crossing of the stent, there is additional suture material put in. Over time, the entire valve, bovine jugular vein, and stent become encased in endothelial scar tissue and become embedded in position.

00:15:32
DOFF McELHINNEY, MD: Yes, that's exactly what's going on. I think we're ready to move forward and get this device out to where it's supposed to go and put it in. So why don't we cut to the table and move forward with that?
00:15:48
JAMES LOCK, MD: We're going to finish the case now, all right?
00:15:50
DOFF McELHINNEY, MD: Okay.
00:15:51
JAMES LOCK, MD: Okay.
00:16:02
DOFF McELHINNEY, MD: As Dr. Lock gets his catheters in the right position, I'm going to start to prepare the valve to put it on the delivery system. There's a tag here that I cut off.
00:16:21
PETER LANG, MD: Can we have the overhead camera focusing on Doff as he mounts the valve onto the balloon catheter? So Dr. McElhinney is holding the valve and the stent and he is going to crimp it onto the balloon so that it can fit within the sheath to be delivered to its correct position. So the first that he's doing is he's holding the valve, he's placing it around a simple syringe, and he's doing the first compression, and what he will do is reduce the overall diameter of the structure by about a factor of 4. And so he is reducing it now around the cylinder of a syringe, and once the diameter is reduced to that size, he will take it off the syringe, and then he will place it around the deflated balloon that is at the end of the delivery catheter. So McElhinney is handing the valve to Dr. Lock. Dr. Lock is holding. We can come in on Dr. Lock's hands a bit. He is placing the valve stent onto the balloon and he is crimping it onto the balloon, which is at the end of the delivery catheter. There is an attempt to make this as tight as you can to reduce the size of the catheter that is needed to deliver the valve. You can see it there. You can also see it on the right of your screen. The catheter has the blue tip, which will pass over the wire and get into position within the conduit that is currently connecting the right ventricle to the pulmonary artery in this patient. The sheath and catheter that are in the body now are being removed. The wire remains as a tract between the patient's groin and the pulmonary artery. The delivery system is now being placed over the wire and now will be threaded from the femoral vein through the inferior vena cava, and then it will go through the heart. And this is one of the more difficult parts of the procedure because it is a rather tortuous course, and the entire valve-balloon-catheter system are relatively stiff, and they need to follow the path of the wire to the position where the catheter will be deployed -- excuse me, where the valve stent will be deployed. So if we can now switch to the AP camera. The darkest part of the catheter is the stent with the valve on it, so that is now in good position, probably just a little bit farther than the position where it will be deployed. I'm just going to ask some questions before -- I think Dr. McElhinney mentioned before we went live with the presentation, the previously placed stent had been dilated to increase its diameter a bit, and then following the dilation, the balloon-sized stent was used to choose the size of the valve to place. There is a super-stiff wire in there which allowed placement of the stiff catheter. The delivery system and sheath are being withdrawn a bit. What you see within the already placed stent --
00:21:51
DOFF McELHINNEY, MD: Peter, Jim's going to start going through this as we're about to put it out here. Okay.
00:22:01

JAMES LOCK, MD: If anything, I want to be a little on the distal side. So you guys are ready there, is that right?
00:22:07
DOFF McELHINNEY, MD: We're ready. Yup.
00:22:09
JAMES LOCK, MD: And he's back inside it. Okay, inner balloon first, please.
00:22:16
DOFF McELHINNEY, MD: Okay, here I go.
00:22:20
PETER LANG, MD: This is a dual-balloon system. There's an inner balloon, which will help stabilize the system, that's now inflated. The lateral balloon, the larger balloon, is now going up.
00:22:33
JAMES LOCK, MD: It's got to go all the way up. Blow it up. Blow it up. Blow it up.
00:22:37
PETER LANG, MD: The balloon in the stent containing the valve is virtually completely inflated. The balloon will now be deflated. This is a live image of the delivery balloon being deflated. The valve and the valve stent are in position within the pre-existing stent.
00:22:27
DOFF McELHINNEY, MD: The problems this patient has had as a result of his leakage has been an abnormal rhythm, an atrial flutter. From the beginning of the case, he went into atrial flutter, which had good rate control because of the medicine he's on, but he's now back into a normal rhythm, as Dr. Lock was just mentioning when he said, "back in sinus." Now that the balloon has been blown up and the stent placed, we have to take the delivery system out and put in a different set of catheters to make more measurements and take pictures afterwards to make sure that the valve is working the way we intended. So, that's what is happening here. The tip you can see there if we can go to a lateral frame. You can see that the dark triangular shape coming down right below the stent is the tip of the delivery system and that has to be pulled across the valve and usually works fine without doing any damage, but that's what Dr. Lock is working on at the moment. And that's gone okay, so we're going to put in a new set of catheters to make measurements and take pictures, and then hopefully everything will look great and we'll be done. So I don't expect that we've got much more here. Might get another --
00:25:15
JAMES LOCK, MD: Peter?
00:25:17
PETER LANG, MD: Yes, Jim.
00:25:20
JAMES LOCK, MD: We couldn't really do this case from the groin last time because, if you'll notice on the AP camera, go to the AP camera, the conduit in this patient is very medial. It's very close to the tricuspid valve, and we actually could not dilate this conduit from a femoral approach when we did it before, so we had to use a rather more complicated wire and catheter course. If you now look on the lateral picture, you'll notice how tight the bend is that I have just below the stents, in an extra stiff wire, and then I have another very tight bend out in the MPa. We couldn't get this wire out into the right ventricular outflow tract without first putting a balloon catheter into the left pulmonary artery to hold it in place while the wire was advanced. But once we got this compound curve on the wire out into the pulmonary artery, it became much easier for everything to go. The other I noticed is that because this patient has had so many attempts at stenting his right ventricular

outflow tract, you can't see the Melody stent. It's inside an old platinum-covered stent. All right, so here we are. So what are we going to do?
00:27:01
DOFF McELHINNEY, MD: We're going to measure pressure, and we can either take a picture with this or put another catheter up and take a picture with that.
00:27:07
JAMES LOCK, MD: All right, let's have a seven pigtail, 100 cm long, please. Yup.
00:27:15
DOFF McELHINNEY, MD: Then we do need to get back into the LV at the end.
00:27:17
JAMES LOCK, MD: And I have to tell you, this was easier than the average case to get this stent into this right ventricular outflow tract. Of the dozen or so cases we've done before this, most of them have been a little more difficult than this, which emphasizes how important it is to get the right wire curve to direct these relatively large catheters into the outflow tract. All right, so now we'll measure right ventricular pressure, and here it is in some fashion. The reason that I wanted to be relatively fast with this catheter course is that the wire was producing catheter-induced heart block for a period of time, and as soon as we exchanged that, as soon as we got rid of the long sheath, it went away. So he's back in normal sinus rhythm. We didn't have to treat the heart block. He's had that on multiple occasions in the past. All right, let's measure aortic and right ventricular pressures here. And we can cut now, and we need the left ventricle.
00:28:39
DOFF McELHINNEY, MD: We do. We can do that after we take a picture, if you like.
00:28:44
JAMES LOCK, MD: All right. Let's do that. And now were going to measure a gradient across this right ventricular outflow tract, so we have the long sheath. It's got to be out there, doesn't it? All right, now what we're going to do is we're going to measure.
00:29:11
DOFF McELHINNEY, MD: Why don't you come back to the angiogram, lateral?
00:29:16
JAMES LOCK, MD: Now we're going to measure pulmonary artery pressure and pulmonary artery pressure. Record this, please.
00:29:23
DOFF McELHINNEY, MD: Show the hemodynamic again, the hemodynamic pressure.
00:29:32
JAMES LOCK, MD: And now there it's below the valve, so this is the right ventricle and main pulmonary artery, and this is really exactly what you would like to see. We have a gradient of 18, and there is a big diastolic gradient across the valve, which indicates that the patient now has valve function.
00:29:57
DOFF McELHINNEY, MD: Can you put this onto the lateral camera now, please?
00:29:59
JAMES LOCK, MD: Let's have flow on the injector. Thank you. And you can fill that. And let's give him -- I don't know, let's give him 30 at 30 right here. We're probably in a little too far, but let's see. Inject. All right, so there's nothing falling back into the right ventricle. We don't see any pulmonary regurgitation here. We'll do it again, 30 at 30, a little bit closer to valve to be a little bit more compulsive. Ready? Inject. And now you can see that there's really no evidence at all. And now we'll measure aortic and right ventricular and left ventricular pressures, and get me a saturation, please. As is often the case, he has a very dilated aortic root and actually hasn't even been that easy to get in.

00:32:07
DOFF McELHINNEY, MD: We can decide not to, Jim.
00:32:17
PETER LANG, MD: As part of our post-implant evaluation, the protocol calls for measuring simultaneous right and left ventricular pressures, which will --
00:32:29
DOFF McELHINNEY, MD: We want to confirm what the left ventricular pressure is afterwards, and he does not have any blockage on that side of his heart, but it's a standard piece of information that we like to obtain.
00:32:41
JAMES LOCK, MD: Okay, record RV and LV.
00:32:42
DOFF McELHINNEY, MD: Okay, can you show the pressure, please.
00:32:47
JAMES LOCK, MD: Wait just a second. Cut. And record MPa and RV and LV.
00:33:02
PETER LANG, MD: The scale here is 100 mm of mercury.
00:33:04
JAMES LOCK, MD: All right, there we go. That's RV and LV. So that's 60 and 105. Cut. Do we need to do anything else?
00:33:21
DOFF McELHINNEY, MD: No, we just need to get pressures on the way out. Right side pressures on the way out.
00:33:24
JAMES LOCK, MD: Okay, record. Actually, cut. Did we hit an aortic sat [in gas]?
00:33:31
FEMALE ASSISTANT: No.
00:33:31
JAMES LOCK, MD: Here's an MPa saturation.
00:33:35
DOFF McELHINNEY, MD: Okay, so that's the procedure, and we're just going to finish taking our catheters out and make a couple more measurements, but the valve is in. It went just exactly as we would have liked and, as you can see, it's completely competent. Now, there's still blockages across that pathway, which has been a problem that multiple stents haven't been able to take care of.
00:34:00
JAMES LOCK, MD: This is probably -- this is RV and AO.
00:34:03
DOFF McELHINNEY, MD: Okay, we can show the pressure again here.
00:34:05
FEMALE ASSISTANT: MPa 77.
00:34:08
JAMES LOCK, MD: RVA packs and RA.
00:34:13
DOFF McELHINNEY, MD: These are the pressures as we come out.
00:34:15
JAMES LOCK, MD: Cut. Keep recording, actually. And here's descending aorta.
00:34:21
DOFF McELHINNEY, MD: Now the pressure catheters come out of the ventricle and into the aorta, the big vessel to the body, and that's the procedure. We're done, and we're going to finish taking everything out and wake him up here pretty soon. You can come back live.
00:34:46

PETER LANG, MD: Okay, I'd like to answer two questions that have come through, two additional questions that have come through over emails. One asks what happens if we don't have as favorable hemodynamics at the end of the procedure. If there's persistent obstruction, the valve may not be completely inflated and the balloon can be redilated there. There's also a question of, "What if there's regurgitation?" Fortunately, we have not experienced that, but there's a possibility of valve dysfunction, incomplete opening of the valve, and the balloon would be blown up again. In some procedures in other institutions in the past, second valves have been placed if there was dysfunction in the first valve.
00:35:27
DOFF McELHINNEY, MD: Right, you can put another one inside of the first one, that's exactly right. And that's been -- about half of the patients who have had to have something done because of leakage or blockage of one of these valves, about half of them have had another valve put inside of the first. The other half have had to have surgery to replace that. Sometimes the conduit that you're putting it inside of simply isn't big enough. The conduits don't grow and the patient hopefully does over time, so the conduit is limited in its size, but that's exactly right.
00:36:04
PETER LANG, MD: All right, I think we will conclude the webcast. We want to thank all of you for joining us, and we'll try to answer the other questions that come through over the Internet. I'd like to thank Dr. Lock, Dr. McElhinney, Dr. Marshall, and Dr. Peng for just a terrific job putting in this valve. Thank you all very much.
00:36:27
ANNOUNCER: This has been a live presentation of a transcatheter pulmonary valve procedure from Children's Hospital Boston. OR-Live makes it easy for you to learn more. Just click on the "request information" button on your webcast screen and open the door to informed medical care.
00:36:59
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