

**REPLAY OF HEART TRANSPLANT PROCEDURE
MONTEFIORE-EINSTEIN HEART CENTER
NEW YORK, NEW YORK
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ANNOUNCER: Welcome to the Montefiore-Einstein Heart Center in New York City. In just moments you'll see the first heart transplant procedure ever webcast on OR-Live. The procedure was performed by Dr. David D'Alessandro on April 17th at the Heart Center. Dr. Daniel Goldstein will moderate a range of discussion topics, including a clinical description of the procedure and aftercare. The operation you're about to see is called the orthotopic heart transplantation. The recipient's heart is taken out and a new heart is placed in the same exact position that the native heart rested in. 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 go OR-Live.

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DANIEL GOLDSTEIN, MD, FACS, FACC: Good evening. Welcome to Montefiore Medical Center in New York City. We're happy you're able to join us either here in the audience or anywhere in the greater New York area, United States, or all over the world. You're in for a special treat tonight. Through the magic of the Internet, we're for the first time ever featuring a heart transplant operation with the possibility of the audience to be joining us in an active interactive fashion to find out more about this very exciting operation. By way of introduction, heart transplantation is really a very radical operation. It's probably one of the most invasive things that a person can have done to them. This is not taking a gall bladder out or taking an appendix out, this is really replacing an old, damaged heart for a new, normally functioning heart.

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By way of history, the first heart transplant operation ever performed was performed in 1967 by Dr. Barnard. Probably most of the audience has heard about that. That patient lived only for 18 days. And in fact, the next nine operations performed around the world were pretty much unsuccessful. And in fact, there was a moratorium placed on heart transplantation in such a way that nobody was allowed to perform another heart transplant operation. Many people in the field thought, "Huh, this is it. We will never see this done again." And in fact, it wasn't until 1983 with the advent of very powerful immunosuppressant medications that clinical heart transplantation became a reality. Nowadays, approximately 2,200 to 2,300 operations are performed in this country and probably around 3,000 worldwide. And the life expectancy of patients receiving this operation is terrific. People who don't receive this operation who are as sick as people who do live in the order of about a year. If you receive it -- if you're lucky enough to be one of the few who receives a heart, you have a 50% chance of being alive close to 12 years. So this is a very powerful therapy for a very bad disease, and the disease we are speaking about here is end-stage heart failure.

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Now, heart transplantation is a unique and rare and unpredictable operation. What do I mean by that? Well, if Mrs. Smith came to my office and she needed a heart transplant, I could not say, "Mrs. Smith, we'll do this operation Thursday morning." It just doesn't work

that way. We never know when a heart is going to become available. A team is always ready, and at the turn of a dime we need to get a big team involved in order to procure the heart, get the patient into the hospital if they're not already in the hospital, and perform the operation. So while the operation itself, which you will view in a few minutes, lasts probably on the order of 45 minutes to an hour, the entire process takes more like 12 to 18 hours. And Dr. Ricardo Bello, one of our physicians, will describe more regarding this process.

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So here we are. Once again we welcome you. We encourage you to email any questions you might have. There's a text box on your screens which will allow you to directly text us, and as soon as we can and as often as we can we'll attempt to answer any questions you might have.

I am the surgical director of the transplant program, but I am not the only person who can do this. I need a whole team of people and talented people to help me. To my right is Dr. David D'Alessandro. David came to Montefiore Center shortly after I arrived. We both trained at Columbia-Presbyterian Medical Center down in -- a few miles down the road. And to his right is Dr. Ricardo Bello, who's one of our very talented residents who actually completed his training at Montefiore Medical Center and is now one of our junior attending physicians. So with not much more to do, I will pass on to Dave so he can describe a little bit about the patient whose transplantation procedure you're about to witness. David?

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DAVID D'ALESSANDRO, MD: Thank you, Danny. This is a real exciting opportunity for us to introduce to you the heart transplantation procedure and some of the tenets involved in the operation. The patient whose operation you're about to see is a 53-year-old gentleman who came to us several months ago with longstanding history of worsening heart failure. This began for him about nine months prior when he suffered a viral illness which left his heart permanently damaged and unable to perform the normal functions of a normal heart. His complaints were mainly shortness of breath and fatigue, and this had again been worsening over the last several months. When he was evaluated here at the Einstein Heart Center facility, he had already been maximized on medical therapy and basically had come to the end of the road. Despite that, several weeks later he was admitted here to this hospital with worsening congestive heart failure and required administration of intravenous medications to help his heart to pump. That still was not enough to relieve his symptoms, and his shortness of breath was so bad that he could not even get himself out of bed. What we had to do was place a special balloon pump in his groin called an intraaortic balloon pump, which basically inflates and deflates and helps assist and unload the heart. We were preparing to put an artificial heart in this gentleman because the balloon pump was a temporizing measure, but fortunately for him he had a less common blood type which enabled him to get a heart much more quickly. Whereas most people on the heart transplant list wait several months, even periods in excess of a year, he was able to get a heart within a couple months of being listed. So when the call came in, we prepared him for the operating room and sent a donor team led by Ricardo Bello on my right to go evaluate the organ. In a minute we're going to cut to the videotape of the operation, which begins after I've already divided the breastbone to gain access to the heart, but why don't we begin with Dr. Bello's description of the organ harvest procedure. Rick?

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RICARDO BELLO, MD, PhD: Thank you, David, and thank you all for joining us tonight. Well, as Dr. Goldstein said, this whole process is very unpredictable, but nevertheless there's always a team ready 24/7 ready to go. From the time that we received our first phone call to the time that the recipient operation is completely finished, it takes approximately 12 to 18 hours, as Dr. Goldstein had mentioned. However, the actual operating time for procuring an organ and for implanting the organ is not nearly as long. So what causes all of these -- why so much time, then? Well, the main reason for this is that there's a lot of delays involved in the process which again are unpredictable to us. For example, normally we

would go to harvest the organs at distant sites, and this does not simply involve hopping in an automobile or a van to get there but usually involves flying there, and so charter flights have to be set up. And this not only occurs for our team harvesting a heart but for other teams harvesting other organs. Once the teams are assembled at the donor hospital and the donor is brought into the operating room, we proceed with the operation. Throughout the operation we're in constant communication, and of course, prior to this the donor's medical records and studies have already been reviewed not only by our transplant coordinators but by the procurement team. Once we proceed with the operation, the actual procurement is very straightforward and takes less than approximately a half-hour. This involves doing some basic dissection to expose the great vessels of the heart and placing a tube in the ascending aorta to allow for delivery of preservation solution. But again, this is something that requires us to be in constant communication with the recipient team back at Montefiore as well as the other teams that are there procuring organs. Once we're ready to proceed, the aortic cross-clamp is placed on the ascending aorta and preservation solution is then delivered to the heart. Ice is placed on the heart that stops the heart and helps in the -- this helps in the preservation of the heart. Shortly after that and over the next 10 to 15 minutes the heart is explanted from the donor and placed in preservation solution and brought back in a cooler full of ice. We of course try to minimize the time that this takes because we try to minimize the total amount of time that the heart is without circulation. And so once the aorta is cross-clamped, we try to speed back to the recipient hospital. Once we get back, Dr. D'Alessandro will be ready to receive the heart and start the implantation. As I said before, the timing is critical. We try to minimize the time that the heart is out of the circulation, and so optimally, as the recipient heart is being remove, we are arriving with the donor heart. Danny?

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DANIEL GOLDSTEIN, MD, FACS, FACC: Thank you, Rick. Just something that the audience might have not picked up on. Unlike kidney transplants, where you can use a cadaveric -- meaning someone who has died -- you can remove their kidney, when you're dealing with heart transplants you've got to remove the heart from a patient whose heart is still beating. So usually in all instances these patients are braindead and the family has been approached after the brain death, which can occur either as a result of drowning or a gunshot wound or a stroke or a bleeding to the head, and they're asked for permission to donate the heart as well as other organs. So just to make that -- that's an important point. This is always a beating heart harvest unlike the kidney and other organs that can be removed after the patient's heart has stopped.

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We have a question here from the United Kingdom. Someone's viewing and asking if the procedure we're about to witness is the same procedure that is done in the United Kingdom, and the answer is yes, with perhaps some minor technical differences, I would say 90% of the heart transplant operations that are performed in the world are performed in the same way that you will say here, namely by a bi-cable technique. So without more to do, why don't we start rolling the tape? David?

00:11:45

DAVID D'ALESSANDRO, MD: Yeah, let's get to the exciting part. So the patient is now in the operating room, and as I mentioned before, the breastbone has already been divided. You see a retractor in the patient's chest that helps us to expose the heart. And just to orient the viewer, the patient's head is at the top of the screen and the feet are at the bottom of the screen. What we're doing now is putting stitches into the aorta. In order to take the patient's heart out, we need to put him on a heart-lung machine. As you might imagine, by removing the heart, we're removing the patient's ability to send bloods to the lungs to oxygenate the blood and deliver that to the rest of the body, so we need a machine that takes over that function while the heart is removed. And that's called a heart-lung machine, and that's operated by a specialized team of people known as perfusionists. And their job is

to keep that blood circulating, to keep it oxygenated, and to keep the body's metabolic mechanisms going while the -- during the period of time when the heart's removed. Now we're putting tubes into the aorta. That's what's called an aortic cannula, which is basically a large hose that goes into the ascending aorta. And that's going to deliver the blood that we're soon going to remove from the patient's body. That's going to deliver it back to the patient's body after it's circulated through the heart-lung machine and been oxygenated. What you don't see is that the superior vena cava, which is the large vein that drains blood from the upper half of the body to the heart that has already had a tube placed in it, and now we're putting stitches on the inferior vena cava, which is the large vein that sends blood to the heart from the lower half of the body. And we call these purse string sutures because of the mechanism by which they tighten, similar to a ladies purse, I'm told. The next thing you're going to see is a -- the cannula that's going to go into the venous side. That's a -- that's a very sharp knife that we use to make a hole, and through that hole we'll place the venous tube.

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DANIEL GOLDSTEIN, MD, FACS, FACC: As we see in these cannulation of the vena cava, we have a few questions we'd like to answer. One of the questions is, "What is the current protocol for screening the donor heart?" There's a number of things we look at in terms of assessing whether a donor is a good donor to supply the organ for a recipient. From a cardiac's standpoint we look at cardiac enzymes. We like to know what the mechanism of death was. We get an echocardiogram of the patient, usually a transthoracic echocardiogram, and we obtain a cardiac catheterization to make sure the arteries to the heart are normal. Clearly we only do this in people who are at high risk at having blockages of the arteries to the heart. So people who are smokers, people who are at advanced age, people who are diabetic, high blood pressure, these are the kind of people which we would consider doing that.

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DAVID D'ALESSANDRO, MD: So what you just saw was placing what are known as tourniquets around the inferior vena cava, and in a few more minutes you'll see another one placed around the superior vena cava. And those are used to create a seal around those hoses so that when we cut the heart out the blood doesn't leak around the cannula. At this point we're creating a tissue plane between the left and the right atria which will assist in identifying the correct areas to cut when we're removing that part. And basically you see the operation's proceeding a bit slower at this point, and that's because we're waiting to hear from Dr. Bello that the organ has arrived within the hospital. We've done nothing irreversible at this point in time. And if there were an accident of some sort that prevented the donor heart from arriving, we could always wean the patient from bypass and return him albeit still with persistent heart failure. So we're waiting to know that that heart has arrived, and at that point you'll see us place a cross-clamp on the ascending aorta and cut out the heart. There is constant communication at this point between our donor team and us in the operating room telling us where they are, how far out they are and basically gives us an idea of how much more time we have to get this heart out. We're now creating a similar tissue plane between the pulmonary artery, which is that structure on the right-hand side of the screen, and the aorta, which is the structure on the left-hand side of the screen that has the large tube in it. And again, that's just to assist us in knowing where to cut. And that's the tourniquet going on and being tightened now around the superior vena cava. So we've now sealed off the inflow of blood to the heart, and you can see how the heart is now emptying. It's become a much more baggy or flaccid-looking structure, whereas before it was quite large and distended and beating weakly. I want you to remember how this heart looks at this point in time because when you see the new heart later on you'll notice that it beats much more vigorously.

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So presumably, Dr. Bello has arrived in the hospital and we're now cutting out the heart, so this begins the first irreversible step in taking the heart out. We're now cutting into the right atrium at the border with a secured vena cava. And what you'll see in a minute are some wires that are coming through the secure vena cava, and that yellow catheter which is a pulmonary artery catheter -- it's a special catheter designed to measure pressures in various spots in the heart, and that's going to assist us in caring for this patient over the next several days. There are special pacemaker wires and defibrillator wires which enter the heart through the superior vena cava that we're now cutting, and those are going to retract back into the superior vena cava. And at the end of the case you'll see us removing those wires and taking that all out of the patient, but at this point we just want to get it out of the heart and out of the way of the secure vena cava that we're later going to need to connect.

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DANIEL GOLDSTEIN, MD, FACS, FACC: David, how commonly do you see these kind of pacemakers and different relays in people having these operations?

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DAVID D'ALESSANDRO, MD: Defibrillators are indicated in patients with severe forms of heart failure as a precaution from cardiac arrest, and that's basically everybody that we transplant, so it's very, very common. It's less common for patients not to have these devices in this day and age than it is to have them. So it's almost a routine first step of the operation is to make an incision over those pacemaker pockets, which tend to be up by the shoulders, and to get them prepared for removal. And it's not much of a nuisance in taking them out. It's really quite simple.

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DANIEL GOLDSTEIN, MD, FACS, FACC: Clearly they have a new perfectly functioning heart, so they will not need a pacemaker or a defibrillator. For those of you in the audience who have a pacemaker, don't fear that you're going to need a heart transplant. Most people who have a pacemaker have it for other reasons and not necessarily end-stage heart disease.

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DAVID D'ALESSANDRO, MD: So we're now separating the heart from its juncture with the inferior vena cava. And that, which you just saw, that rather messy maneuver, was us cutting into the aorta. And as you might imagine, the aorta is still under pressure, and so when we first incise that, there's quite a release of blood. But you'll see in a moment that that quickly clears. And the field that we're operating in remains relatively free of blood for the remainder of the operation. We're now dividing the aorta and the pulmonary artery, and we're going to be lastly taking out the left atrium of the heart. Now, when heart transplants were first performed, the connection to the pulmonary veins used to be connected individually, and there are four of them. And they're rather difficult to see, and they can be rather cumbersome to connect. So Dr. Shumway many years ago showed us a very simple way of connecting that to the left side of the heart, leaving a cuff of the left atrium, the patient's own left atrium, in the body. And maybe we can pause the tape for just a minute.

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DANIEL GOLDSTEIN, MD, FACS, FACC: Can we pause the tape, please?

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DAVID D'ALESSANDRO, MD: If we can get a closer view of that. It may be a little hard to see.

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DANIEL GOLDSTEIN, MD, FACS, FACC: Would it be possible to pause the tape as the heart is coming out? Is it possible to rewind? Thank you. In the meantime, I have two very interesting questions. Francesco, he's asking me whether animal hearts have ever been used in human heart transplants and why we're not doing these. Those are not allowed for various reasons. The most immunologically reasonable organs to be used would be from a baboon because baboons are the closest animals related to humans. Unfortunately, because

of the animal rights and ethical issues, baboon hearts are not being used in that setting. Most of the experimentation going on in animal hearts relates to the use of pig hearts. Pig hearts are abundant. A lot of people eat ribs and eat pork these days, and so there's no problem in killing pigs and taking their hearts out. The problem is there's such a huge immunological barrier between the antigens of the pig and the human antigens that we most of us in the field don't believe that a xenotransplant will ever occur. Can we advance the film a couple of steps here?

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DAVID D'ALESSANDRO, MD: Okay. So you'll see as the heart comes out what's left is the cuff of left atrium, which connects to the four pulmonary arteries.

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DANIEL GOLDSTEIN, MD, FACS, FACC: And there you see it. You see the heart coming out. So what you're staring at is really an empty chest there. There's nothing there except some tubes. So the patients are in suspended animation.

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DAVID D'ALESSANDRO, MD: This is -- we've obviously passed the point of no return, so we are confident at this point that our new organ has arrived and that it's going to work. You can see the pulmonary artery catheter that I showed you before, which is that -- that yellow structure, and later on in the operation you'll watch us as we reimplant that, reposition it rather, into the -- into the new heart. So the -- Dr. Bello has just brought the -- the harvested heart out of the cooler and it's now up on the operative field. That's sitting in some ice-cold saline. And the next several minutes we are preparing this heart for implantation. And the first thing that's often necessary is to sew up any holes in the donor organ, and this particular hole was made purposefully by Dr. Bello in order to vent it. And it's a small incision in the left atrial appendage, and we quickly sew that up with some prolene suture. This suture that you'll see us using here is this blue-colored suture. It's called polypropylene, and it basically feels and acts a lot like fishing line. It glides rather easily through tissue, which makes it very easy to work with, but it does require several knots to secure. So at this point we are separating the aorta, which is the structure on the bottom that we're -- looks like a long tube. And this is now the pulmonary artery, which branches into right and left. And we're going to open that up and create one large tube. And again, we're just getting all these structures ready to sew, so we have to make them symmetric in appearance so that there are no major gaps which might lead to bleeding. We're going to remove excess fat or excess blood vessel that's going to make things too long and lead to kinking. And this still is the pulmonary artery, which we want to shorten quite a bit. And again, we want to try to make that as symmetric in appearance as possible to minimize any chance that that might bleed later on in the operation.

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DANIEL GOLDSTEIN, MD, FACS, FACC: As you're completing here the maneuvers, Dave, there's a person who says, "My brother at age 43 received a heart transplant at an institution and he just celebrated his 64th birthday," so this person has been alive for 21 years with a heart transplant. Is he unusual or just lucky? I would say both. As I stated earlier, the results of heart transplantation are such that 50% of patients are alive 12 years. Your brother is certainly lucky and obviously very well-treated, and he's been alive for 21 years. I would say around 15 to 20% of patients will live that long with a heart transplant, so continued good luck.

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DAVID D'ALESSANDRO, MD: That's always nice for us to hear. Now we are preparing the left atrium and again doing similar things. We join all those pulmonary veins and we make one large cuff here, and this cuff will later be attached to the left atrial cuff that we left in the patient's chest that I was describing earlier. And the last thing that you're going to see us do in just a minute is check for any congenital holes that might exist in the heart, the most common of which is known as a patent foramen ovale, which is that area that we're

probing right there. And this person did not have one of those, but they're fairly common even in normal patients. And when we see them, we like to close them. Generally that just takes a very quick suture in that area of the heart.

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So now we've taken the heart out of the ice bucket, and you might notice that this heart is considerably smaller than the one we took out. Most normal hearts are about the size of your fist. The one we took out of our patient was considerably larger than that, but this is a normal-sized heart and much more size-appropriate for this normal-sized patient. The first stitches that we're going to put in are in the left atrium, and it's really critical as the heart starts to go in that we have it properly oriented, and when there's no blood in the heart and it's not beating, you can easily get disoriented as to what goes where. But we want to make sure that nothing's twisted and that it sits anatomically in the chest. So these first sutures are really critical. And there are special alignment sutures that we use and tricks that we've developed over the years that help us do this with relatively minimal errors. So these first few sutures are going to go in, and we're going to in a moment parachute this down, and that's exactly how it sounds. We're going to put the first three stitches in. That's going into the recipient left atrial cuff. And now it's going to -- the next stitch will be down into the -- I'm sorry, that was the donor left atrium, and this stitch is going into the recipient left atrium. After we get the first three sutures in, we drop the heart down by pulling tension onto both sides of that stitch and it gradually tightens as it goes down. It's now much easier because things are aligned, so we know where each successive stitch is going to go by how the tissues line up as they go in. So in essence, each stitch sets up the next stitch and it makes things lie rather nicely so that we can put it in.

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DANIEL GOLDSTEIN, MD, FACS, FACC: Can we pause the film for a second? Thank you. Are there any questions from the audience? We have a very robust audience here at Montefiore. And if there are any questions, feel free to raise your hand and I'll attend to them. There's a question here of how long will the surgery last. I'm not sure they're asking how long the webcast is going to last. The surgery itself takes about an hour, and hour and 15 minutes in the standard routine operation. If someone's had prior surgery, if they have an artificial heart in place that needs to be removed, then the operation can get more complex and can last many hours. In the back of Dr. D'Alessandro's mind and Dr. Bello's mind at this point as you're watching the operation is a little tick-tick-tick, a little thing that reminds you you know this heart cannot be outside the body more than four hours. And we like to -- at that point we start having increasing incidence of heart failure. The recipient heart begins to fail. So we like to keep that time, what we call cold ischemic time, to no more than four hours. By that reason if we got a phone call from San Francisco that a heart was available, we probably would not take that heart because that would require a five-hour trip and an extra half-hour travel in the airport and then another hour to the operation room. We're talking about six, seven, eight hours, so we don't travel transcontinentally to obtain hearts unless we're dealing with a very young neonate or something like that where hearts are not as readily available. Let's go back to the tape.

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DAVID D'ALESSANDRO, MD: As Dr. Goldstein just mentioned, as this heart is being in, it's really not being kept cold except for intermittently when we deliver a preservation solution, which you'll also see in a moment. So we're also thinking as this goes in that we have to protect this heart from becoming too warm before we reconnect the blood supply because that's when damage to the organ can occur. So we're trying to get this heart in as quickly as possible and -- but carefully and safely so that we do not have bleeding problems once we reestablish blood flow. So we're now finishing up the left atrial cuff anastomosis, and those first several sutures were put in from the left side of the table. You see that we sometimes will change hands depending on who has an easier position at the table to get the stitches in. So we're finishing up those last several sutures on the left atrium and we're

going to secure that stitch in just a moment. So then here come the knots, and you'll see that we've also learned to tie knots rather quickly because we do it fairly frequently.

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And the next anastomosis that we are going to perform, or the next connection, is the inferior vena cava. So we just delivered cardioplegia to the aortic root there. We sort of edited that out a little bit. But that gives some cold preservation solution to the heart to cool it down again because of those several minutes when we had it in the chest cavity where it really gets rewarmed quite a bit from circulating blood from the patient. The inferior vena cava connection, which is this one we're doing now, can also be somewhat difficult to do because it's low down in the chest cavity and there's often a fairly marked size mismatch because we're connecting a vein to basically the left atrium of the patient. And we have special tailoring techniques that we do to make sure that that connection is sound, it's not too tight, and again, that you want to make sure that it's not twisted. So this requires a lot of manual manipulation so that we can show the surgeon exactly where the next stitch goes in. And unfortunately for our viewers, that doesn't leave a lot of room for us to see what's going on down there.

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DANIEL GOLDSTEIN, MD, FACS, FACC: Can you pause the tape a second? David, if you could answer a couple of questions from our international audience. How long can a patient be left in the heart-lung machine without experiencing undesirable effects?

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DAVID D'ALESSANDRO, MD: Excellent question, and I'm not sure anyone knows the exact answer to that. We in general think artificial circulation, or circulation of blood through a heart-lung machine is not physiologic. It's not great for patients. And we know that the longer you keep patients on heart-lung machines, the more complications you have with inflammation, with organ dysfunction, with possibilities of stroke or other neurocognitive events. So there is no set time limit to how long we think is safe, but in general we like to limit that to as little as possible. Now, most patients for heart transplantation, even if we're removing an artificial heart or doing something more invasive or more complex than what you're seeing here, those bypass times are usually limited to periods under four or five hours, and that's considerable longer than usual. For our routine heart transplant operation like you're seeing here, bypass times are in general considerably less than two hours unless you have to resuscitate the heart for prolonged periods of time. But historically, patients have been on heart-lung machines for periods in excess of 24 hours, although the chances of getting complications goes up quite a bit as you exceed periods of about four to six hours.

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DANIEL GOLDSTEIN, MD, FACS, FACC: There's another quick question here. What would happen if the donor heart was not received in a usable manner? Could the removed heart be reimplanted? Well, clearly, David has already told you that we've got to make very sure the heart is in very good condition before we even cut it out from the donor. So once the heart is cut out from the donor we've checked EKGs, cardiac enzymes, echocardiograms cardiac catheterization, Dr. Bello, the harvest team has already visualized the heart. So we're very sure that the heart is going to be very usable, and nothing usually happens during transport as long as the transport doesn't exceed a couple of hours. So could the heart be removed, be implanted? It could in theory, but that heart is a very sick heart that has not received blood supply and is now sitting in a bucket without blood supply for a couple of hours, so the answer is no. Once the heart is cut out, that's it, we're done. We have to use the new heart that's coming. Let's go back to the tape, please.

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DAVID D'ALESSANDRO, MD: So I might only add to that that it is sometimes necessary to add other means of support to a new heart that's not functioning as we expected it to. That's very uncommon but sometimes requires special assist devices. And we never like to see that, and fortunately that happens very infrequently. These are the last several stitches

going into the inferior vena cava, which remember, is the large vein that delivers blood from the lower body into the lower part of the left atrium. And you might -- left atrium.

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DANIEL GOLDSTEIN, MD, FACS, FACC: Right atrium.

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DAVID D'ALESSANDRO, MD: Right atrium, I apologize. And you might appreciate there that there's some excess tissue that is being implanted into the inferior vena cava. And when that's all said and done, that's going to look like a connection that God might have designed to be there.

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DANIEL GOLDSTEIN, MD, FACS, FACC: I'm being asked how will I reduce the rejection chances, and that's a good question. What you're seeing here is the exciting, perhaps the sexy part of heart transplantation, but in all honesty, the art of heart transplant lies in the immunosuppression management of these people after heart transplantation. Once the surgery is done and the heart is doing well, clearly the fine balance that needs to be worked out is between not giving too much immunosuppression and rendering the patient prone to infection and not enough immunosuppression where the patient can reject their own heart. So that's truly an art that requires usually a cocktail of three medications that act at different limbs of the immune system. So in terms of what are the chances of rejection, I would say we've gotten so good at it that the chance of acute rejection between the first year of heart transplant is less than 10% in most active institutions.

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DAVID D'ALESSANDRO, MD: All very good questions. So we still are seeing what I thought before were the last several stitches. I guess I was wrong. We have several more to go. But in a moment you're going to see this connection completed. The next anastomosis that you'll see after those knots are tied down is the superior vena cava, and again, that's the large vein that delivers blood to the upper part of the right atrium from the upper part of the body. And here again we're delivering cardioplegia again to the aorta, and we do that through the catheter that was left in the donor heart, and we leave it there so that we're able to intermittently resuscitate this heart with cold, protective solution while we're putting it in. And again, just trying to protect that organ as best we can to minimize the possibility that that organ might have damage and might not work as well as we would like when we finally remove that cross-clamp. So this is now the back wall of the superior vena cava, and as you might imagine, we have to connect the back wall before we can get to the front wall, otherwise it becomes rather difficult to see. And as we're putting this connection in, you'll notice that those veins seem to fit rather well together. And that's very important. We have to cut those veins to the exact size that we think is necessary. If you leave them too long, those veins can kink, or if you cut it too short there can be tension on the anastomosis, which might lead to pulling on the sutures and bleeding.

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The other things that we're very aware of as we are sewing these two vessels together, these two in particular, is that that suture that we used doesn't cinch up on the vessel, causing a stenosis or a blockage, which might impede blood flow to the heart. Here we are using a special clamp and we're putting that pulmonary artery catheter -- we're repositioning it back into the heart, and that went into the right atrium and up out of the pulmonary artery, and that's pulling it out of the pulmonary artery right there. And later on we will position that in the more -- the more distal or faraway branch of the pulmonary artery, which is where it's going to sit for the next several days and again help us manage the patient.

00:36:15

So we're now completing the front wall of that vein, and you can see the pulmonary artery catheter sitting very comfortably in there. No longer is there any defibrillator or pacemaker leads within the superior vena cava, so it's a nice, wide open vein, and we want

to make sure that we keep that wide open, so we sort of lock those sutures as we put them in to prevent them from structuring, or purse-stringing. And that's the completion of the anastomosis, and then we'll tie that suture down or knot it, and then we'll move on to the next connection.

00:36:53

DANIEL GOLDSTEIN, MD, FACS, FACC: Just to reiterate for the audience, there's five connections that need to be done: the superior and inferior vena cava, the left atrium, which was the first one to be done, then the pulmonary artery and the aorta. So there's five connections. That's the most common way this operation is done. Alternatively, and in the past, it used to be done only with four connections so that we instead of having a separate superior and inferior vena cava, we just have a right atrium to right atrium connection. But it's been found that those kind of connections are more prone to distorting one of the valves inside of the heart and it more commonly leads to atrial arrhythmias, so by and large that kind of technique is abandoned in most centers.

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DAVID D'ALESSANDRO, MD: So again, this technique that we're showing you is a bi-cable technique as opposed to a bi-atrial technique. And this is now the pulmonary artery, and you can see we are again cutting this even shorter than we had cut it previously. And that's because now that we see how the heart lies or is positioned in the patient's chest cavity and we see where the patient's own pulmonary artery lies, we want to again make sure that this is the exact right length that we think it needs to be. And if it's too short, it may pull, and if it's too long, it may kink, so this we really feel is critical to get these connections just right. Now, we are going to -- that's the pulmonary artery catheter. We're now going to position that in the patient's pulmonary artery, and that's going to go down the right pulmonary artery in this instance. And you can see that that -- and that's where it's going to sit, again, for the next several days, and we'll use that to help monitor the patient's cardiac output, which is a measurement of how much blood the patient's delivering into and out of the heart and also the various pressures within the chamber, which give us a lot of information about how well the organ's working.

00:38:38

DANIEL GOLDSTEIN, MD, FACS, FACC: Can we pause the film for a second, please? There's a very interesting question, Dave, that I'd like to address. This is a question most people ask when they hear about heart transplant is, "Is there an order of priority as to who will be the recipient?" Is this a random event or is there a very well-defined set of criteria as to who is going to receive a heart?

00:38:56

DAVID D'ALESSANDRO, MD: Well, that's an excellent question, and fortunately, there is a very well-designed set of criteria, and that's based on an organing body -- or organization that helps -- that has created a waiting list of patients. And it has to do with what region of the country or the world you might live in, but in this particular country it's divided up into regions. And those patients that are sickest or who have been on the waiting list the longest get preference to others. Outside of that, it takes into account things like blood type. As you might imagine, blood-typing is very important in any kind of organ -- well, most kinds of organ transplantations. And also, the patient's size. You might imagine that if we put a very small heart into a very large patient, such as Dr. Bello here, that might not work so well. So size is critical. So those four things are very important in deciding who's going to get a particular organ.

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DANIEL GOLDSTEIN, MD, FACS, FACC: So very important. If you have two recipients that look exactly -- they have the same blood type, the same size -- the person who is the sickest will get the heart first. So it makes sense that you don't want to let someone die so that someone else who could wait another week or month or year is not going to receive that heart. It just doesn't make sense. So it's a very fair system. There's always issues

surrounding it, but we -- most of us in the field feel that the UNOS, which is the governing body of -- it's the United Network for Organ --

00:40:21

RICARDO BELLO, MD, PhD: Sharing.

00:40:22

DANIEL GOLDSTEIN, MD, FACS, FACC: Sharing -- thank you, Rick -- governs distribution and allocation of organs. Why don't we go back to the tape?

00:40:32

DAVID D'ALESSANDRO, MD: So we are nearing the completion of the operation and we are connecting the pulmonary artery. Again, this is the -- this is now the fourth connection. The final connection will be the aorta. Once we reconnect the aorta, we are going to reestablish blood flow to the patient's heart, and usually we will see the heart begin to beat at this point in time. Now, this particular patient had a fair amount of pulmonary artery return, which you're not appreciating right now because we have a suction catheter in the patient's pulmonary artery. But when we complete this anastomosis, or this connection, you will actually appreciate that the heart will begin to beat, and that's because although we have not restored the normal circulation, the patient's heart -- or the new heart has begun to see a small amount of blood circulating, and it will begin to have an organized rhythm, or heart rate.

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So we're now connecting the pulmonary artery. This particular vessel is rather floppy, and again, it can be quite easily twisted or placed in such a manner that it doesn't sit well within the cavity. So we're very aware as we're putting these stitches in and we're reassessing things as we go to make sure that the size is correct and that the alignment is correct, and in this particular instance, I'm sure you'll agree that it looks quite nice.

00:41:56

DANIEL GOLDSTEIN, MD, FACS, FACC: I have an interesting question here from the audience. We're getting a barrage of questions. This is very exciting for us here. But it says, "Can the artificial heart Jarvik perform the same purpose as a human heart transplant?" That's a tricky question. The shorter answer is yes. There's a total artificial heart. There's a lot of devices that can be used to support the heart, but there's really only one total artificial heart that can be used to replace the heart. So you would remove the heart just like we did now and use a new completely artificial heart. The heart is made by Abiomed -- it's called the AbioCor -- but its use is very limited to a very selective group of patients who cannot be supported any other way. Our sense is the artificial heart as a clinical device will probably not be used to replace heart transplantation, but more likely we will have more and more and smaller and more sophisticated left ventricular assist devices, which are smaller pumps that assist the failing heart. So the heart, the sick heart, is not removed, but a machine is attached to it to help it beat and perform its function. David?

00:43:03

DAVID D'ALESSANDRO, MD: So this is -- back to the patient's aorta, we're now trimming the patient's aorta. And you can see the cross-clamp still just above where those scissors are being applied. And that cross-clamp is separating our operative field from a very large amount of circulating blood. And in a moment after that connection is established, we're going to release that, and that will restore blood to the patient's coronary arteries, and the heart at that point in time will begin to beat quite vigorously. And you'll notice that the heart has already started to beat, and that is because there is a small amount of blood circulating through this heart, albeit at a low pressure, and that's supplying just enough blood to resuscitate the electrical activity to the heart. And I think you can appreciate that the aorta is quite a bit of a more robust vessel than the pulmonary artery or those other veins that you saw us sewing earlier. Sometimes looks like a piece of calamari in thickness there. And it holds sutures quite nicely. This vessel in particular is under quite a bit of pressure, so we have to be very aware that our sutures are going in at the proper depth

and at the proper spacing, especially in this part of the vessel that we're sewing now. This part of the vessel we're going to have a lot of difficulty seeing later on in the operation, and if there's any bleeding from that suture line, we will have difficulty controlling that. So we're very careful at that part of the connection. We're now moving our way up the left side.

00:44:34

DANIEL GOLDSTEIN, MD, FACS, FACC: Can we pause the tape for a second? I have some wonderful emails here that I must share with you. And I've had now three or four heart transplant recipients that are getting in touch with us. One of them says, "Do most transplanted hearts restart when blood supply is reintroduced? Do many have to be shocked to start beating properly? And thank you, donor families, for allowing your loved ones' organs to allow us to go on. I am out 11.5 years." Dave, can you answer those questions for us?

00:45:06

DAVID D'ALESSANDRO, MD: Most hearts will begin to beat spontaneously once you reestablish blood flow. Now, that rhythm is not always organized, but in general, once we see that heart begin to move in some manner, we're all quite relieved that we know that heart's going to be okay. Most of the time it's an organized rhythm and we might have to start some medications to assist that heart in beating more vigorously, but it will start to beat. And if the rhythm is unorganized or in some sort of a fibrillating rhythm, we do often need to give it one or two shocks of electrical energy in order to sort of jolt that heart back into an organized rhythm. But once that's done it usually beats just fine on its own and there's very little we have to do to assist it.

00:45:47

DANIEL GOLDSTEIN, MD, FACS, FACC: Quick question here. Did I understand correctly some of the old heart was left in and the new heart was attached to a part of the old heart? The answer is yes, we leave a cuff of the aorta, a cuff of the pulmonary artery, a little piece of superior and inferior vena cava, and the large part of the left atrium intact. Let's go back to the tape, please.

00:46:08

DAVID D'ALESSANDRO, MD: So we're now completing the aortic anastomosis, and again you might also notice that this is a larger structure than some of the other connections that we had. So this is the final phase of the operation. As we're again putting these sutures in, we want to make sure that the spacing is just the way we want it and that the size of the two vessels match. There are occasions where the donor aorta is either considerably smaller than or considerably larger than the aorta that we're sewing to. And when that's the case there are certainly tailoring techniques that we sometimes need to employ in order to get that fit just right. But the basic tenet is we need to make a good seal and we need to make sure that connection is nice and wide open and there will be no obstruction or turbulence in the blood flow. And that was the last suture, and that's the securing knot that's going to secure that connection. And the final thing that you'll see after we release those cable snares, those snares that prevent the inflow of blood to the heart, and that's removing the cross-clamp right there. So we've now reestablished blood flow to the heart. We have a suction catheter in the ascending aorta that's removing any stray blood that might be leftover in the chambers of the heart. And those little air bubbles can cause real problems if they get down into the coronary arteries or travel elsewhere. So we leave that catheter in there to remove any stray air that might have been left behind.

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And you'll notice in a minute that the heart will really start to beat quite vigorously, and the first several beats are often less vigorous, but you'll see that that quickly changes. And the other thing I hope you can appreciate is that this heart is considerably smaller than what you saw when we first opened the chest. The patients with longstanding heart failure, their hearts tend to get quite large and the cavity that contains the heart correspondingly gets quite large so that the new hearts often look like small peas in a large pod. And that's

sometimes quite marked in appearance. And what we -- these final maneuvers we put these temporary pacing wires on the heart. These are pacing wires going on the ventricle. We'll later add some pacing wires onto the aorta. You'll see as we go that the heart is really beating quite vigorously now.

00:48:24

DANIEL GOLDSTEIN, MD, FACS, FACC: The magic of heart transplantation.

00:48:27

DAVID D'ALESSANDRO, MD: And that is a very normal-looking decompressed heart. That's what we like to see when we're all done. So we've now -- are weaning the patient and we've resuscitated it now for several minutes on the heart-lung machine to allow this heart to recover slowly. We don't want to shock it. And so once we think that heart is ready to take on the work of supplying blood to the lungs and the rest of the body, we slowly take them off the heart-lung machine, we open up those vessels that are taking blood away from the heart so that the heart is now getting the full supply of blood from the patient's body, and then we ventilate the lungs again and we turn off the heart-lung machine. This patient is now completely surviving on the new heart that we just put in, and that's always exciting to see. And these are now drainage tubes which we're leaving behind. You might imagine that that space that once contained a very large heart is now a potential space that can collect fluid or clot or other things that might inhibit this new heart's ability to work the way we want it to work. So we leave all these drains behind to prevent that fluid from accumulating. And this is a larger tube that again serves the same purpose, just keeps that heart nice and dry and free of any unwanted fluid that might collect around it.

00:49:42

DANIEL GOLDSTEIN, MD, FACS, FACC: Will you stop the tape for a second? There's a question from a -- I guess he's a urologist who's joined us. He says, "Is there a certain stitching pattern that must be followed, like that of stitching a new-formed bladder or the urethra?"

00:49:55

DAVID D'ALESSANDRO, MD: No. I think you urologists have developed all sorts of fancy techniques for connecting ureters, or the tube that connects the kidney to the bladder. Fortunately, we've not needed to be so clever. So we use a standard running suture on most of these connections, which is basically just and over and over stitch that pulls through the tissue as we go. We find that to be -- create a very nice seal and to be watertight. It very nicely prevents bleeding. Now the only caveats to that are those that I described earlier, where that sometimes has the tendency to purse-string suture, or to tighten it as it goes in a manner that we're not anticipating. So there are certain locking-type sutures that we'll throw in on occasion just to prevent that from happening to make sure those connections remain wide open and don't obstruct any blood flow. That's a very good question.

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DANIEL GOLDSTEIN, MD, FACS, FACC: As we finish the tape here, just Rick, can you comment on what happens -- what are the things you worry about once the patient gets to the intensive care unit? You've closed the chest. Patient's on a couple medications. What are the early things you worry about as a heart surgeon that can happen to a patient in the first few hours after heart transplantation?

00:51:07

RICARDO BELLO, MD, PhD: Well, the primary thing we worry about is bleeding. Bleeding in and of itself, the initial treatment is transfusion and making sure that the blood is clotting properly, but those transfusions can then affect the transplanted heart, and so if we suspect that there's any bleeding, we would want to return back to the operating room and address that as quickly as possible. Other than that we worry about the patient's hemodynamics, or blood pressure, and blood flows, and we manage that with medications. There are frequent

adjustments to the medications early on. So those are the major things that I think we tend to worry about.

00:51:47

DANIEL GOLDSTEIN, MD, FACS, FACC: You see on the film as David and Rick are finishing the finishing touches on hemostasis, or stopping any potential bleeding there from the bone marrow. Another thing we worry about is the issue of right heart failure. You must remember, people who have heart failure have very high pressure on their lungs because they've been having -- they had left heart failure for a long time. And now you're asking a new heart that was beating inside a normal person to pump against the high pressure in the lungs. So we're very cognizant and wary about right heart function right after the operation, and to do that, to manage that, we maintain the filling pressure to a certain level, we use what we call inotropic medications, or medications to help the right heart beat better. We're very careful how much fluids are going into the patients and how many fluids are going out of the patient. So that's one of the issues besides the bleeding, which is the most common one that we follow immediately after transplantation. Once the initial few-couple days are by and the patient is stable, usually within 6 to 12 hours the patient is removed from the breathing machine if everything else is okay. And then we start introducing the immunosuppressant medications slowly. And from then on is the -- really the art of transplantation, as I mentioned earlier, is basically preventing rejection from happening while not allowing the patient to get infected. And that's a team effort. It's done by our heart failure colleagues at this institution: Dr. Simon Maybaum, Dr. Julia Shin, and Dr. Ron Zolty are involved in the management of our patient postoperatively in this regard. Are there any questions from the audience at all? Yes, Dr. Attai?

00:53:35

DR. ATTAI: [unintelligible]

00:53:52

DANIEL GOLDSTEIN, MD, FACS, FACC: That's an excellent question. We explain to every question this is really a marriage. They're getting married again. And they're getting married to us, and they married a big team. This is not Danny Goldstein or Simon Maybaum, this is a whole team that's required to really have a successful heart transplant program. There's a surgical team, which is a team you've met today, there's a medical team headed by Dr. Simon Maybaum, and there's a cadre of very hardworking transplant coordinators that make it all happen. These -- in our program there's four women who take call every night, field a lot of phone calls. Many times they're up in the night and then it turns out that the organ is not usable. And they're really our front line, they're our cannon fodder, to use a term, but they're the ones that really seek out all of the problems, put out all of the fires and let us know what's happening. And they really are the engine of the program. So you need transplant coordinators, you need surgeons, you need an anesthesiology team to do the transplant, you need a perfusionist to run the heart-lung machine, you need the medical doctors to make sure they're giving the right immunosuppressant medications. And usually the protocol after transplantation, it varies from center to center. But by and large, patients remain in the hospital after everything goes well about a week or two after surgery, at which time if they're capable they go home to begin their recovery. They're seen every week for the first four to eight weeks. They have a heart biopsy. This is very important. The medical team performs a biopsy of the heart by a small incision made in the neck. It passes an instrument right into the heart and takes a piece of the muscle. Then it's sent to the pathologist to review to make sure that the patient is not experiencing a rejection. And that's done quite frequently: once a week for the first eight weeks or so and then it's spaced out every two weeks to every four weeks and then monthly. By the end of the year -- by the beginning of the second year they're doing this every six months or so. So this is what we call surveillance biopsies. If there's a change in the clinical condition and we think the patient might be rejecting, then that biopsy is done in an urgent manner. The patient is brought into the hospital and biopsied as necessary. But this is a lifelong intervention.

Patients need to be seen frequently, they need to be very in touch with their body. A little fever in a normal person like you and I, Dr. Attai, would just lead us to take a Tylenol or two. In a patient, a little fever can unmask a life-threatening infection within 24 hours. So usually we tell our patients, and we repeat it to them and to their families, that any little cough, any little shortness of breath, any little symptom that a normal person will disregard should prompt contact to the medical center, and that is key.

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One of the issues about addressing who is a candidate for heart transplantation, it's a very important question. And in general, each patient -- any potential candidate is examined from head to toe literally. We've got to make sure that the heart is basically the only thing that's wrong with a patient. If a patient has a heart that's not functioning or the kidneys are not good and they have a history of depression and perhaps their liver function is not normal, those people are not candidates for heart transplantation. We need to be very restrictive because we have a donor crisis. There's about 2,200 donors available a year. It is estimated that in this country if criteria were loosened, 60,000 to 100,000 patients could benefit from a new heart. So we need to -- so you're talking about a ratio of 20:1. So we need to be extremely selective. And a big part of the selection process is assessing the compliance of the patient. If the patient's smoking every day and then go out and have a couple drinks every day, we cannot offer a heart to those patients. If they have an unstable social environment where they don't have a family or loved ones who are going to help them through this very difficult process, then it becomes more challenging to offer a heart to those patients. So yes, Dr. Attai, it's a whole team effort. And the follow-up after the operation, after the procedural from the hospital, is a very, very serious and thorough one.

00:58:05

DAVID D'ALESSANDRO, MD: Just to clear up any misconception, Danny mentioned that our team of coordinators were made up of four women. You do not need to be a woman to be a coordinator. We are an equal opportunity employee --

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DANIEL GOLDSTEIN, MD, FACS, FACC: Thank you, David.

00:58:18

DAVID D'ALESSANDRO, MD: Employer, and we will consider anybody that we feel will be suitable for that position.

00:58:24

DANIEL GOLDSTEIN, MD, FACS, FACC: Thank you, sir.

00:58:25

DAVID D'ALESSANDRO, MD: Are there any other questions we can answer from the audience? Dr. Michler?

00:58:30

DR. MICHLER: [unintelligible]

00:58:52

DANIEL GOLDSTEIN, MD, FACS, FACC: Thank you, Dr. Michler. Dr. Michler, just so you know, is our chairman of our department of cardiac surgery here, and between him and the rest of the team, we've performed over 500 transplant operations in the past few years. So we're fairly comfortable with this operation. Dr. Michler asked a very good question. What is the quality of life of a patient receiving this operation? Are they on pins and needles and sitting by the phone waiting to get sick? We usually don't offer an operation unless we can -- this kind of operation -- unless we're sure we can do two things: one is improve the survival of the patient, which we do categorically without question. Number two, that we can improve the quality of life for the patient. If they're alive but sitting on a ventilator, well, that's no quality of life. I don't think anybody would accept that as a good outcome. So these people have an absolutely normal life. People have gone back and actually participated in the Olympics, they have run marathons, they've climbed Mount Everest. They have really a normal life and much like you see the heart after the completion of the

operation, if I didn't -- if you didn't know this patient was a heart transplant and you opened the chest, you would not know this patient had had a heart transplant unless you saw those suture lines. Much in that way, the patient feels pretty normal and looks pretty normal to you and I after the operation. On occasion, some of the patients -- because one of the immunosuppressant medications or steroids, they tend to gain a little weight and get a little puffy on the face and in the back, but that tends to resolve over time as the steroids are removed. So the answer to the question, to have a superior quality of life that has not been matched to date with all the artificial heart technology that we have. So there's nothing like the organ that God gave us.

01:00:34

DAVID D'ALESSANDRO, MD: And I would add that they become quite savvy with medicine. They've become -- not only with their own body but as far as medications, the interactions of medications, and when warning signs creep up, they know when to call. So these patients often after being within the clinics for several years will know more than many of our medical staff.

01:00:58

DANIEL GOLDSTEIN, MD, FACS, FACC: If there's one more question we can entertain, otherwise -- otherwise we'll complete our transmission. Any questions from the audience? Yes, Dr. Attai. One last question.

01:01:13

DR. ATTAI: [unintelligible]

01:01:16

DANIEL GOLDSTEIN, MD, FACS, FACC: Thank you. The question is what is the age limit of transplant? Dr. Attai, you're too old and you're in too good health and your heart is too strong, so you don't need to worry about it. In most program in this country, the age limit is 65 years of age. Our program tends to be a little more relaxed. We tend to transplant patients out to ages 69. There's a couple centers in this country that use what we call marginal organs, so the organs are not perfect, they're slightly less than perfect, and we'll relax the criteria for inclusion into candidacy for transplant and we'll take patients in their early 70s. But by and large, age 65 is the cutoff for most programs.

01:02:00

DAVID D'ALESSANDRO, MD: Dr. Attai, we would consider you for a donor.

01:02:05

DANIEL GOLDSTEIN, MD, FACS, FACC: With that comment in mind, we thank very much the audience here in New York, in the U.S., and around the world for joining us in this exciting event. Thank you very much.

01:02:20

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