CARDIAC RESYNCHRONIZATION THERAPY
HARTFORD HOSPITAL, HARTFORD, CT
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NARRATOR

Heart failure affects more than 20 million people worldwide and nearly 5 million in the United States. The failure occurs when the heart becomes damaged or weak. Eventually, it is unable to pump enough blood to meet the body's needs. The heart may also be unable to synchronize all segments of the pumping chamber, causing a dysynchronization. Doctors at Hartford Hospital in Hartford, CT, are treating patients with the disease using a procedure called cardiac resynchronization therapy.

CHRISTOPHER CLYNE, M.D.

The main purpose, as I said, of this surgery, is to resynchronize abnormal segments of the pumping chamber. In order to do that, we need to place pacing electrodes or stimulating wires in different areas around the left ventricle.

NARRATOR

Cardiac resynchronization therapy is an option for patients with moderate to severe heart failure and ventricular dysynchrony. When a heart failure patient has ventricular dysynchrony, the two lower chambers beat separately. Cardiac resynchronization therapy sends tiny electrical pulses to both the right and left ventricles to make them beat at the same time. The procedure has shown encouraging results among heart failure patients. You are about to see a live webcast of a cardiac resynchronization procedure from Hartford Hospital in Hartford, CT. During the presentation, you may send questions to the faculty at any time by clicking the email button below.

JEFFREY KLUGER, M.D.

Good evening. I'm Dr. Kluger and I'm live in the control room at the Hartford Hospital interventional EP laboratory. This evening we'll have the privilege of observing Dr. Clyne and his team implant a resynchronization device for this gentleman. Dr. Clyne, would you like to introduce your staff?

CHRISTOPHER CLYNE, M.D.

Thank you, Jeff. Yes, right next to me is Dr. Magdy Migeed, one of the senior electrophysiologists in the arrhythmia section here at Hartford Hospital and an expert in

this implantation procedure. Rosemary Carr will be assisting us in the procedure and Marie Brennan will be circulating today. Jeff, just prior to this filming, we have been working on our patient, getting access to the implanted defibrillator which was put in 3-4 years ago. This particular device is at the end of its battery life and needs to be replaced. Our patient has had progressive heart failure symptoms over the last 6-12 months and now is extremely limited in his ability to perform his activities of daily living. He's been evaluated with tissue Doppler echo studies as well as EKG and echo analysis of the pumping function of his heart. We think he'd be a very good candidate, not only for replacement of his battery, but upgrade at this time to a resynchronization therapy device for congestive heart failure. The device is explanted from his chest, viewed here. You can see the various defibrillator leads emanating from the pocket in his chest. This lead that I'm holding in my right hand is actually a guide wire that was placed percutaneously through the pocket into the subclavian vein. Now, if you look at the camera showing the AP view of the patient's chest, the movement of that wire shows you how it courses from the axial and subclavian vein under the clavicle into the great vessel area, the superior vena cava. You can see there's a lot of traffic there. The defibrillator lead with the large coil that you see right there. That's the atrial lead that looks like a J, screwed into the right atrial appendage. Just there, you can see our guide wire in the bottom of the right atrium. This is a patient who has had a defibrillator patch placed prior to the use of endocardial defibrillator leads. You can see the outline of that patch right on top of the endocardial defibrillator lead, which was placed several years later into the right ventricular apex. Now, at this point we have access to the right atrium. We're going to go back up to the subclavian vein and the superior vena cava and we're going to thread the dilator sheath over the retained guide wire and that will give us a passageway, if you will, into the patient's venous system and, from there, into the chambers of the heart. You can see that this guide wiring isolates, contours the sheath into the superior vena cava.

Now, right at about that point, right there, as you can see when I wiggle that, that's the end of the sheath that allows us access to the central venous circulation. This is what this looks like. This is the peel-away sheath. That can be removed after the procedure, once the lead is in. We simply crack the spine of that sheath and peel it away from side to side. If done properly, it leaves everything in place and you can remove the hardware.

This, maybe Dr. Migeed can explain to you as I'm putting this through, what exactly this arrangement entails.

MAGDY MIGEED, M.D.

The green sheath is the sheath through which we're going to have a catheter. The catheter's purpose is to go into the os of the coronary sinus. As you can see now, Dr. Clyne is going to go with this tip of the catheter through that sheath that we have already in the patient. We're going to try to get into the coronary sinus. We're going to show you that this is a deflectable catheter. You can see that the tip is going to be moving. I'll show you that.

CHRISTOPHER CLYNE, M.D.

Once we map the intracardiac electrograms of the right atrium and find the area of the opening of the corona sinus or the ostium and we'll intubate the coronary sinus with the electrophysiology catheter, the steerable mapping catheter. Once we have confirmation by analysis of the electrograms within the coronary sinus, then we'll simply thread over this EP catheter, this long coronary sinus guiding sheath. In that way, we'll have access to the coronary sinus. This is an AP view. Right now, because I happen to get a lot of help from the lateral camera, I'm going to bring in the lateral camera, which shows us the version of the heart in lateral view. You can see up top there, the right atrial lead bouncing in and out of view. That square wire to the right of the screen is actually the patch on the left ventricle, so this is a nice landmark for where the coronary sinus should be. Now, back to the AP plane...I'm having a little bit of resistance up top, so we'll try to see what we're dealing with up here. You can see, there's my lead. I have to redirect this beyond all that traffic to course down the superior vena cava and into the right atrium.

JEFFREY KLUGER, M.D.

Chris, can I just make a comment to the lay audience? The coronary sinus is actually a giant vein that drains the venous blood from the left side of the heart to the right side of the heart. This is what enables Dr. Clyne and Dr. Migeed to take the lead from the right side of the heart and actually place it in the left side of the heart through the venous system.

CHRISTOPHER CLYNE, M.D.

Thank you, Jeff. That's a really key point. Of course, if we didn't have access to that coronary sinus, all of this would have to be done through the arterial side of the heart and that would be a different procedure altogether. We're heading out to the right atrium here and getting caught up, I think, in some of these other wires that are there.

JEFFREY KLUGER, M.D.

Chris, while you're doing that, why don't we just look at some background information for the audience.

CHRISTOPHER CLYNE, M.D.

That's great. That will give me a chance to free this lead up and go from the right atrium into the right ventricle.

JEFFREY KLUGER, M.D.

Let's just talk a little bit about the background of heart failure and why this is such an important procedure for this gentleman. For the lay audience, heart failure is quite a complex clinical syndrome. It is defined by the heart's inability to maintain adequate cardiac output to help the person achieve whatever the body needs to perform a particular

activity. As was mentioned in the intro, heart failure is quite a prevalent problem, affecting 5 million Americans in the United States and over 20 million people in the world. Unfortunately, the incidence of this problem is increasing at a pace rate of approximately 2 million a year and 500,000 in the United States. The important point to also appreciate is that heart failure knows no gender difference, with both men and women equally at risk for developing heart failure. Unfortunately, as our population in the United States and elsewhere gets older, the incidence of heart failure also increases substantially. How are we doing, Chris?

CHRISTOPHER CLYNE, M.D.

Fine, Jeff. I have a long guide wire now into the right ventricle and I think we've got probably a fair amount of chronic tissue shelving around those old leads. We found our way through that, into the right ventricle. We're going to put the long guiding sheath over the guide wire in order to safely access the right atrium and right ventricle, and then we'll pull the guide wire out and go through with our intra-atrial mapping to look for the coronary sinus. Right now we're just preparing the dilator for the long sheath. So Jeff, maybe we can mention to the audience that the proper or successful access of the coronary sinus, even though almost everybody has it, 1 out of every few thousand patients or so was probably born without a coronary sinus, which makes it very difficult then to find, but the distortion of the heart during the dilatory process in heart failure patients makes the coronary sinus a very difficult structure to find in many patients because of the variation in anatomy, so it's not always a slam dunk to get this thing in there. We're going to hope that in this patient it goes very smoothly. We're now down into the right atrium with our sheath and our dilator, which you can see.

JEFFREY KLUGER, M.D.

Chris, while you work on that, I'd like to answer an email, if I may. The email question is, in your view, what are the pros and cons of percutaneous placement of a coronary sinus lead versus the thorascopic placement of a left ventricular epicardiac lead in cases where achievement by resynchronization is difficult?

CHRISTOPHER CLYNE, M.D.

That's a great question. You know, initially this whole procedure was done through a thoracoscopic approach, so there's a lot of historical data. Like most open surgical procedures, although now with a scope it's a little bit less rigorous for the patient and less morbidity, there was some early mortality in very sick patients and I think most people were very uncomfortable with a thoracotomy. Even a limited thoracotomy is something that most people would like to avoid, so maybe morbidity or just discomfort of the procedure is one thing. I'm sure there are surgeons who have had experiences where patients tolerate it very well.

In truth, epicardial leads do not last as long as endocardial leads in patients with chronic pacing devices. Now, for a procedure that lasts a couple of hours, with good stable lead

position, we expect these leads to last a decade or more, while screw-in leads on the outside of the heart, because of contact with the chest wall and constant banging of the outside of the heart to localized tissue, can actually have a much shorter life span. So I think comfort – most of these patients will leave the hospital within about 24 hours – and longevity of the lead is probably two of the important reasons.

Very importantly, when we access the coronary sinus and therefore the left ventricle from the inside or endocardially, we have really an open view of many different vein sites on the left ventricle to choose from. I think it may be more difficult to access parts of the left ventricle through a scope where we get optimal hemodynamic results.

JEFFREY KLUGER, M.D.

Thanks, Chris. Dr. Clyne is somewhat modest about the fact that in this new biplane EP lab, it's very unusual not to be able to adequately place a coronary sinus lead into an appropriate vein. So, although historically, at the beginning of this transvenous procedure, there were a certain number of failure rates because of the inability to access the coronary sinus and the venous system on the left side, with the expertise we have here at Hartford Hospital in this wonderful new laboratory, that's really not the case.

CHRISTOPHER CLYNE, M.D.

Jeff, thanks for that lead-in. I just want to point out that while we were talking, we were actually able to access the coronary sinus. I want to point out to the audience the three views, if you will, that we use to make sure we're in. To the far right is a physiologic recorder where we see the electrograms of the coronary sinus. You see the large atrial electrograms followed by very small ventricular electrograms, reported from the tip of our EP mapping catheter. So by electrogram analysis, we would say yes, this is a position very consistent with the coronary sinus not, for instance, in the right ventricle. Now on the left lower camera you'll see in an AP view, the coronary sinus is intubated with the EP catheter. You see that moving out of synchronous timing with the lower and larger defibrillator catheter, so you can see the different movement of the left side of the heart, which is represented by the coronary sinus catheter or the EP catheter, and the right ventricle, which is represented here by the defibrillator catheter.

Now we're going to go to the next camera, on the right side. This is our lateral view. Now, remember I said that patch was outside the left ventricle. Well, look where our EP catheter is. It's right over that patch. This is why we use the coronary sinus. We have a perfect access to the left ventricle through the coronary sinus. The trick here will be to thread the sheath over the coronary sinus catheter without removing it because you can see there's a very right bend here and this is sometimes quite difficult, so we shimmy this. We have to shimmy up and down when we push forward on that guiding sheath. Now you can see our guiding sheath is in place and there is our coronary sinus catheter, verified not only fluoroscopically but electrically, by electrogram analysis, and our sheath is about at the mid body of the coronary sinus, seen here on the lateral view, over to the right, and I'm wiggling that coronary sinus catheter.

I'm going to remove the coronary sinus catheter. First we're going to save this image so that I can come back to it if I need to see exactly where the ostium is. Here is the lateral that we're going to see. We'll use these later when we need to come back to the cut films or the frozen images. I'm going to turn this over now to Dr. Migeed. We have access to the coronary sinus and Dr. Migeed will do the central venogram to show everybody, including ourselves, what the venous pattern is and what we might access for optimal left ventricular placement.

MAGDY MIGEED, M.D.

We're going to actually do this in LAO and RAO view. That was a nice job. Dr. Clyne actually got into the coronary sinus very quickly. The first thing I'll do, actually, is just make sure...the key here is to try to get into the coronary sinus without causing trouble. Trouble means dissection.

JEFFREY KLUGER, M.D.

Magdy, actually that brings up an email question about what is the surgical backup in the event that there is a problem with perforation?

CHRISTOPHER CLYNE, M.D.

I can address that, Jeff. As we schedule patients, we have a checklist of things that we get. We use tissue Doppler echo scanning before anybody actually comes to the OR, to make sure that not only are they dysynchronous, but we know what walls are most dysynchronous. We then look at various 3D spect images, again to confirm that dysynchrony for placement. We also contact our surgical colleagues and we let them know of the date of our procedure to make sure that one of them will be available, should there be a need for acute pericardiocentesis.

JEFFREY KLUGER, M.D.

Thank you, Chris. Dr. Migeed is repositioning the fluoro equipment to visualize the introducer. LAO refers to left anterior oblique image position.

MAGDY MIGEED, M.D.

So, this is the balloon-tipped catheter. A balloon-tipped catheter can be very stiff, so we have to be very careful when we approach the heart. One thing we do is, we checked already the balloon, make sure there's no leaks in the balloon. We have at this point a contrast medium that we will inject into the coronary sinus. Now I'm going to get an AP view. Now you see that I'm advancing. I inject a little bit of dye to try the catheter so you can see it. We then advance the catheter until it gets just about to the tip of the sheath. We have to be very careful of that. We haven't gotten there yet, but it looks like we might be getting close. So it's coming just outside the tip. Now, one thing we can do is withdraw

the sheath a little bit. I just did a little bit of an injection, just to see where we are. Now the balloon is up and when we're ready, we can inject the contrast medium and take a picture of that.

Another thing we have to mind is to immediately deflate the balloon. You don't want this balloon to stay up. These are very important things to do. Now can I have a look at the picture we recorded to try to study the branches and try to select a branch that is optimal to place the lead.

CHRISTOPHER CLYNE, M.D.

I'll just interject here, Magdy. With this system, we have a running image of our venogram, as you can see. We'll get the injection and I'm going to freeze that and put it up top so we can look at that. I'm now going to go back to that same series and I'm going to freeze the lateral view so we can get a good image of that lower posterolateral branch that you see. It's frozen now in the lateral projection and in the AP projection, top left AP, top right strict lateral. In our laboratory, posterior is to the right, to the back of the patient on the right. The front of the patient is toward the left.

MAGDY MIGEED, M.D.

You can see the leads coming down through the long sheath. Now, at that point you can either try a stylet or a guide wire. We're going to try a guide wire for that point. This is an over the wire lead, so we can always use that. So we are advancing a wire through the lead, as you can see here. Again, we have to be careful when that wire comes out. You don't want to cause...I'm going to pull the lead a little bit backward and try to go back in.

CHRISTOPHER CLYNE, M.D.

Magdy, what branch would you be most happy with?

MAGDY MIGEED, M.D.

Posterolateral branch. You want to be close to the base, lateral posterolateral. You want to stay away from the anterior branch.

JEFFREY KLUGER, M.D.

Chris, while Magdy is working on accessing that branch, do you have time to answer an email? The question is, have clinical studies determined the length of time successful results will last? Meaning, is there some loss of effectiveness over time and does that then require repeat procedure of some kind?

CHRISTOPHER CLYNE, M.D.

Well, the short answer is, the early studies that were started in the mid-90s, most recently published in 2000, 2001, 2002, we're out to about 3 years. Mustick from Europe, about 3-4 years of data, show continued improvement in baseline heart failure symptoms.

The longer answer is that, having done several hundred of these here and following these patients as we do, as you know, a lot of these patients will detune and maybe after a year or so come back and say, geez, I felt so good for that first nine months or a year or two years and now I don't feel so good. Now, sometimes that's from a late dislodgment. Sometimes it's from evolution of the dilatory or remodeling of the heart in a patient who has cardiomyopathy. We may, for instance, recently we saw a fellow who did great for a long time and then we had problems. We looked at his echo again and we found that his right heart had dilated as part of this myopathic process. The septum, because it was pulled over to the right ventricle, was now again dysynchronous. Well, in reoptimizing the program parameters of his defibrillator pacer, we were able again, I think, to improve his symptomatic state significantly. We think that 3-4 years out, most of these patients who respond continue to respond and they may, on occasion, need to be looked at and reprogrammed or optimized.

MAGDY MIGEED, M.D.

The sheath is just about up at the os.

JEFFREY KLUGER, M.D.

What you're seeing on the screen now is a combination of the sheath, which is that hollow tube, and then there's a black button somewhere in that tube and then there's a thin wire that is sort of moving around. That is actually the guide wire that's going to access and find a vein. Now you can see the lead actually going over that guide wire, into a branch of a cardiac vein on the left side of the heart. I think that's one of the advantages of doing this approach transvenously, because you can pick optimal veins, whereas if you do a thorascopic echocardial approach, you're kind of stuck accessing the left ventricle where you've made the hole in the chest, so this is obviously a much more sophisticated and accurate way of achieving resynchronization therapy.

CHRISTOPHER CLYNE, M.D.

I'd like to point out that where we are now, I'm going to have to torque this lead a bit to see if I can coax it down. This is a high probably lateral branch of the coronary sinus. What I don't know yet is whether this will give us a good pacing threshold. It may be an atrial branch of the coronary sinus. We would like to have a more posterior branch, so I'm going to actually remove this and I'm going to try to get this, if you look at my template, right above you can see the coronary sinus venogram that was performed, there's a nice posterolateral branch right where it ought to be. It looks beautiful and I'm going to try to get that. If you look up there, it looks like I'm already into that vessel. See the wire? I'm going down a nice posterolateral branch right now. Now, that's just fine. The problem from my standpoint, a little bit with the posterolateral branches, although

they are textbook for placement of the coronary sinus lead and hemodynamic benefit, this vein is likely to course right over the phrenic nerve, so I am going to test it because that looks like very nice position. As long as we don't have phrenic nerve stimulation, we might just take that. That looks pretty good. So we're going to now test.

Jeff, this is a unipolar lead, so a couple of things to remember, all of the manufactured leads today that are available are unipolar, so even though they have an IS-1 terminal pin, you have to remember that they're unipolar and if you try to pace from the leads with your program system analyzer, you're just going to get a lot of noise. It doesn't mean you're in a bad position, but when you place these, please remember to hook into the pocket. Two reasons: One is it'll allow you to pace, as we're doing now, so it looks like we have a pretty good position. I'm not seeing or feeling any diaphragmatic stimulation, so that's a good sign. The other thing is, we want to know if this is going to benefit the patient, if it's going to take one of the segments of the left ventricle that is very late and allow it to be paced at the same time as the more normal or more septal parts of the left ventricle, so if you now look up to the upper right hand screen, you're going to see, on top, the electrogram during pacing from the left ventricle and, down below, the intracardiac electrogram, what we're measuring from inside the heart.

Now, in the patient's own native rhythm, right here, his intrinsic rhythm, what we're going to do is show you the delay of the lateral left ventricle from the surface QRS. So this tells us how late the far lateral wall of the left ventricle is in comparison to the earliest ventricular activation. Here, it's about 170 milliseconds from the beginning of the QRS. That's how long it takes for that left ventricle to really be at the height of its electrical activity during systole. That's a very late segment. What this tells us is that by bringing this dysynchronous segment of the left ventricle in maybe 100 more milliseconds, we're going to be able to resynchronize and optimize this patient's ventricle. This is, in my opinion, a good predictor of the ability to resynchronize the heart. So we're going to take this position.

Now we're going to check at 10 volts to see if there's any diaphragmatic stimulation from this area because of the proximity to the phrenic nerve. In the lateral view at the lower right, you can see the tip of our pacing lead. It's very posterior; that's toward the back of the patient, in the left ventricle, and you can see the separation from the tip of that lead to the defibrillator lead in front of it. There's a wide separation, so we can assume that by pacing from the tip of that lead, at the same time we're pacing from the tip of that lead, we're going to be able to bring in very wide segments of the left ventricle to near simultaneous activation. That's the whole beauty of this. That was 10 volts, Emily? Do it one more time, but I did not feel, nor did I see any diaphragmatic stimulation. That's perfect, so I think we're in a very good threshold. What's the threshold, Emily?

EMILY

The threshold is 1.4.

CHRISTOPHER CLYNE, M.D.

1.4, 1.5 milliseconds. I think we're going to take that and consider ourselves lucky, so I've disconnected. We have a very late signal. We have a position that looks excellent in both AP and on our lateral camera. We have no diaphragmatic stimulation. I think we're ready to hook up to the patient's pacing defibrillator and then we're going to do hemodynamic testing.

JEFFREY KLUGER, M.D.

Chris, while you're hooking up, I'd just like to address some of these email questions that have come in. One question is, are there any limitations in the use of common drugs in congestive heart failure after the procedure, drugs like Digoxin, beta blockers, ACE inhibitors, calcium channel blockers. There is no interference between the use of a resynchronization device and any of the typical drugs that are used in congestive heart failure. One point that needs to be made, though, and this is something that we've seen a number of times as we follow people up in the clinic, is that, given the advanced nature of congestive heart failure, many of these patients are on very high doses of drugs, especially diuretics. After resynchronization therapy, their need for that amount of medication diminishes, so it's very important that the clinical cardiologists, in conjunction with the electrophysiologists, anticipate the need to adjust medication, as sometimes these patients do get into trouble in becoming overly dehydrated and hypotensive.

CHRISTOPHER CLYNE, M.D.

Thank you, Jeff. That's perfect. The other thing I would add to that is that of course the use of some of these medications in patients who have cardiomyopathies and arrhythmia problems, like Amiodarone, for instance, might increase the pacing and defibrillation threshold, but that doesn't necessarily interfere with the implant process or device, but if patients lose capture or if they have problems later on with defibrillation, of course medications can contribute to that.

JEFFREY KLUGER, M.D.

One other thing the audience may not appreciate, the concept of resynchronization therapy relates to the pacing from the left and right side of the hearts simultaneously. The ICD or implantable cardioverter defibrillator that this gentleman had and is getting a new generator that will be able to defibrillate the heart as well as pace the heart. We have predominantly moved away from pacing-only devices, since most of our patients who are candidates for resynchronization therapy are also candidates for the implantable cardioverter defibrillator because of their risk for life-threatening arrhythmias.

CHRISTOPHER CLYNE, M.D.

Thanks, Jeff. Jeff, I'm going to now remove the peel-away coronary sinus guiding sheath, which is done with a splitter for this particular system, which is a Medtronic system. I just have sort of become used to this particular splitter. There's a number of splitters available. Some of the other manufacturers don't use a splitter. They have a sheath that actually will pull back right over the lead, which is kind of a nice trick. I know Dr. Migeed likes the silver splitter, but I just haven't gotten very good with it yet, so I'll stick to the old favorite.

I think at this time as well, one of the things that we do is, before I pull the sheath out, I'm going to put a guide wire into the coronary sinus because it's not uncommon at the time of the sheath removal that the lead, which is tenuously placed anyhow until it becomes a little bit fixed into the coronary sinus venule, it may be dislodged as I pull the sheath out, so we're going to put a wire through the sheath and let it sit in the coronary sinus so if the lead comes out, at least we'll have ready access to the coronary sinus for another pass. I'm going to show you here the AP and there's that wire headed right up into the coronary sinus. Hopefully we're going to leave it and not have it come out. Then we'll remove this guiding sheath and sew the lead down after we test it and we'll do some hemodynamic testing, just to be sure we're going to have a decent effect, but I think this posterolateral branch is really optimal, given the electrical characteristics and the data that we were able to get from the tissue Doppler echo beforehand.

Now, what we do here is, everybody takes part. Some people watch the tip and some people watch the elbow. What is important is that we remove this and that none of this moves, which is not happening. Let's get this out of the way. We're still in good position. Jeff, I'm going to give it back to you while I reassess my sheath.

JEFFREY KLUGER, M.D.

Actually, one of the emails that came in asked the question, what course of action is taken if the lead can't be placed? Hopefully that's not a situation that we have to deal with very often, with the advancements in lead technology and the availability of a biplane laboratory that we have at Hartford Hospital.

The other part of that question was, can you affect the diaphragm with electrical pulses? As Dr. Klein had mentioned, because the lateral vein is near the phrenic nerve and the phrenic nerve stimulates the diaphragm, if your output from your pacemaker device is high, it may stimulate the diaphragm and have people kind of twitch a little bit. It's not a painful issue and it's not a permanent problem. Very often, if it does occur after the lead is placed and the person leaves the laboratory, we often program around it, using the programmer and noninvasively adjust the settings of the device to take away that diaphragmatic stimulation, but it in no way is threatening or a concern about permanent damage to the diaphragm.

CHRISTOPHER CLYNE, M.D.

Jeff, Magdy and I have removed the sheath. You can see the lead, which is to the AP camera. Just to the left of the screen, to the left of that J, coursing down the right atrium and into that coronary sinus, the posterolateral vessel, it hasn't moved. We have a little bit of slack before the right atrium. In the lateral, you can see again that there is some slack. We want a little bit of slack, not too much, but just enough. Now, at this time we still have the guide wire in there, the 0.014 whisper guide wire. I'm going to remove that. Again, we're going to watch the tip very closely and watch the elbow. As we pull the guide wire back, we want to make sure the lead doesn't coil on itself. If there's a lot of torque built up in that lead, it can slip right out of the coronary sinus. These are critical times. Placement is only half of the battle. Then getting the sheath out and getting the guide wire out without displacing the lead is really where the other half of the battle is won.

Now, it looks like we're in pretty good shape here. I'm going to hook up again to the lead itself. At this point, instead of connecting to the pocket, the skin itself, or the muscle in the pocket, I'm going to use the distal defibrillator coil from the right ventricular implantable cardioverter defibrillator because that, in fact, will be the grounding electrode or the anode for this pacing system, so I'm hooked up now. The distal pacing terminal pin is on the left ventricular lead and the proximal pacing electrode or connection is hooked up to the right ventricular tip electrode, the defibrillator electrode into the right ventricle. This is what it looks like. We're going to look to see a 12-lead electrocardiogram on the bottom right panel. We've changed our screen from an intracardiac electrogram to just a standard 12-lead ECG. You'll be able to see, as I disconnect our patient, here's what the patient's intrinsic left bundle branch block ECG shows. We have a long PR interval, which is a little tough to see on this screen because we're at 50 mm/sec, but we do in fact, you can see the P-waves up there in lead 1 and we have a long PR interval. We have a left bundle branch block pattern. Now, as I hook up, you can see there's a chance in the axis, so we used to have a left bundle superior axis. We now have a right bundle with a far rightward axis in a superior to inferior direction, so top to bottom, which of course is more normal than the apex back to the base, so we have normalized or more toward normal the axis of synchronization or depolarization. We're going to check thresholds. Good, 0.9 volts at 0.5 milliseconds and the impedance is steady. Great. So we're now going to sew this lead in place after I irrigate.

JEFFREY KLUGER, M.D.

Chris, while you're going that, can I ask you a question? What's your experience in terms of the age of the patients that usually receive this kind of therapy and is there any age limitation?

CHRISTOPHER CLYNE, M.D.

Well, I think in the general experience, the mean age is probably in the early to mid 70s, which will track in North America and most parts of Europe the incidence of coronary artery disease and congestive heart failure. We have put devices in patients in their early 30s and we have put devices in patients in their late 80s, so the mean age again, probably

early to mid 70s and the range is anywhere from...sorry, I'll take that back. 21 or 22 years of age to 85.

JEFFREY KLUGER, M.D.

Thank you. Interesting question about whether pacing from the left side of the heart has an effect on the QT interval. I would imagine the resynchronization therapy actually over time would help in the remodeling of the heart, which would actually shorten the QT interval, which is one of the manifestations of a dilated heart and congestive heart failure. So what's been observed over time is that the size of the ventricle shrinks as the end diastolic and end systolic volumes are reduced. That, I would imagine, would actually reduce the QT interval over the follow-up.

There's one other question about the company whose device is being implanted here. Since this is not a commercial, what I'd like to do is just share with you the fact that the availability of devices comes from a number of companies that we use at Hartford Hospital. That includes Medtronic, Guidant Corporation, as well as St. Jude Medical. All three companies have devices available, although the Medtronic and Guidant devices are the only ones that are commercially available to us at this time. We're very fortunate, with the quality of the technology, that the device companies have provided for us and have really revolutionized the way we manage many of our patients that otherwise would not do as well as we see them doing with resynchronization therapy.

How are we doing, Chris?

CHRISTOPHER CLYNE, M.D.

Good, Jeff. I'm just sewing the lead down by its anchoring sleeve to the floor of the pocket so that hopefully it won't move. Once this is done, we will connect to the new defibrillator pulse generator and we'll do some hemodynamic testing by altering the AV delay. It always impresses me how much difference we see, sometimes with only 20-30 milliseconds difference in the AV interval. Now, when we do this as an outpatient, we of course look for mitral inflow and some of the other things, including velocity time interval and pulmonary vein flow. We have a lot more, I think, tools to look at what's truly happening in the clinic setting, but there are things that one can do and that we do routinely in the operating room to have some idea, at least, that the patient is going to respond or to give us some idea how they'll do. We have a continuous blood pressure reporting line in every patient. Often our anesthesia colleagues are able to place an esophageal velocity time integral Doppler probe that gives us instantaneous cardiac index. Unfortunately, a lot of patients, like today's patient, we just can't get a good envelope. We tried for about 20 or 30 minutes before the case to get a good envelope, which would tell us the patient's cardiac index. It just wasn't possible, so we don't have that today, but we did do hemodynamic testing and it gives us some idea of how these patients are going to respond, but also how to program them at the time before they leave the hospital. I think it helps. I think it really helps them. So we'll see a little bit of that in

a minute. We're just kind of closing off the insertion site here because there's a little bit of bleeding.

JEFFREY KLUGER, M.D.

Chris, you make a good point about optimization of this technique. Although our tools are somewhat limited during the implant procedure to what Dr. Clyne just mentioned, in terms of hemodynamic monitoring, some of the esophageal probe capabilities, we do have a very sophisticated echocardiographic laboratory here that we utilize and we're able to optimize the settings of the device that actually improve the hemodynamics beyond what we can appreciate in the laboratory. Also, in the event that things change a little bit, we have the opportunity to program through the device, noninvasively, the AV interval to then optimize the hemodynamics. Actually, it's really remarkable to see the reduction in the degree of mitral regurgitation and improvement in cardiac output by just moving the AV interval, as Dr. Clyne mentioned, so it's quite amazing technology and the capability is almost endless for us. I think we're very fortunate to be in the field that we are in as we move forward in this.

CHRISTOPHER CLYNE, M.D.

Jeff, we're just at the time now where we're actually hooking in. This is a high energy pacing defibrillator with biventricular resynchronization capability. This patient has a very dilated heart. He has class III-IV congestive heart failure symptoms. By virtue of placing his last defibrillator, we know that he has very high defibrillation thresholds, so we've opted right from the get-go to use a high energy device, which is a little bit bigger, actually a fair amount bigger than a standard device.

JEFFREY KLUGER, M.D.

While you're putting that into place, a very important question just came by. The question is, it's well known that patients with congestive heart failure have a poor prognosis, mostly those with New York Heart Association class III or IV, as you just mentioned, the important question is does this procedure make this prognosis better, as good as improved comfort of life? I think this is a very key question here. From the beginning of this procedure and for many years, the research was really focused on improving the quality of life and exercise tolerance and hemodynamics of these patients, but recent study was performed, called the companion trial, which actually convincingly showed a very marked improvement in survival in patients who received resynchronization therapy compared to people who did not, so I think not only do people feel much better, but they're living longer and I think that's the key to the success and the importance of this procedure. I think one of the reasons why we are moving away from just pacing therapy alone and including the ICD, because these patients are not dying so much from congestive heart failure, but they're at risk for life-threatening arrhythmias, so the combination of the resynchronization therapy plus the implantable defibrillator is a win-win situation for these patients.

How are we doing?

CHRISTOPHER CLYNE, M.D.

Oh, good, just taking my time, making sure I put in the square blocks in the square holes and the round blocks in the round holes.

JEFFREY KLUGER, M.D.

That's a good thing to do. One other question that came by is what percentage of these systems are put in by surgeons versus cardiologists? At Hartford Hospital, we have a very close relationship with our surgical colleagues, but now almost all of our devices are put in by our interventional electrophysiologists, Dr. Clyne and Dr. Migeed. The surgeons have an expertise and they back us up in the event that we do need that expertise for epicardial leads, but as I mentioned previously, having the special experience and expertise of Dr. Clyne and Dr. Migeed at Hartford Hospital, we have not really needed to involve our surgeons in the routine implantation of these resynchronization devices.

CHRISTOPHER CLYNE, M.D.

Well, Jeff, we're just about ready to put this completed device into the pocket. Let me clean it off, make it nice and shiny, and coil all the leads. With the Richardson, we're going to slide this into the completed pocket, with a little help from my retractor. After this is in, you can see there's a lot of hardware in there. I'll tuck that in. These leads will fly all over the place, so we won't see this but we'll actually tack the floor of the pocket closed at its incision site so that the leads will remain in the pocket and not find their way through to the skin in 3-6 months, where we find that's been a problem for some patients. There you go. So that is the total operation. That wound will close very nicely and hopefully this patient will benefit significantly. I don't know what his main arterial pressure was before. Maybe we could ask our anesthesia colleague. We haven't moved the arterial line at all. I've come up a little on the heart rate because of moving him around, but his pressure now is actually extremely hypertensive at 164/100.

JEFFREY KLUGER, M.D.

Chris, we're going to have to wrap up now. We'd like to thank you and your staff for doing a superb job. Actually, I didn't mention, I've been following this gentleman since 1988, so this is actually a very personal experience for me and I'm very grateful to Dr. Clyne and Dr. Migeed for helping this gentleman, who is quite an otherwise vigorous and active gentleman. Hopefully he will benefit as expected from this procedure.

I would like to thank our audience for joining us this evening. I hope you've had a good experience and an educational experience. I know for me this was a very important opportunity and I'd like to inform you that the archived version of today's program will be available shortly, so please check back on the website or refer to the program link or refer the program link to your friends and colleagues. With that, I wish you a good night.

NARRATOR

This has been a cardiac resynchronization therapy performed live at Hartford Hospital in Hartford, CT. For more information, to make a referral, or make an appointment, click on the buttons below.