Heart Repair: Closing a Patent Foramen Ovale (PFO)

Baptist Cardiac & Vascular Institute
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Good afternoon and welcome to Baptist Cardiac and Vascular Institute in beautiful Miami, Florida. I’m Dr. Jonathan Roberts. I’m an interventional cardiologist here at Baptist Cardiac and Vascular Institute. And we’re so pleased that you’re going to be with us for the next hour to learn about closing a small defect in the heart called a “patent foramen ovale.”

I’d like to introduce my colleague, Dr. Ramon Quesada who is an interventional cardiologist and who’s going to be closing this defect. Ramon, tell us where you are in the Cath Lab and a little bit about your patient.

Yes. Thank you, Jonathan. Good afternoon, everybody, or morning, or evening, depending on where you are. Welcome to Cardiac and Vascular Institute. This is our Cath Lab. This is not an operating room; this is the endovascular suite, meaning that we do procedures here based on imaging and not by incision. We have a lot of people here, my assistant Claudia; Dr. Ralph Machado [PH], Chief of Cardiac Anesthesia, which is helping our team; I have our nurses, Natalia, Rosa, Paul; Mario, our echo technician; and our nurse and anesthetist, Katia Ramirez [PH].

Welcome, everybody. This is a very interesting case of a procedure that we do in young and elderly patients also. This is a 29-year-old female who had two strokes, one recently with no apparent cause. So, all the neurological workup that was done on her was totally negative. The only source of these – possible source of these strokes is embolization coming from a little tunnel in the heart that Dr. Roberts will talk to you about. Jonathan.

Thanks, Ramon. I’d like remind the viewers we’d like for you to participate, and if you have a question during the broadcast, if you look on your screen there’s an “Ask a question” button, and you click that and e-mail us in a question so that you can participate.

I’d like to go over the anatomy a little bit of the heart to give you a better understanding of what we’re doing and why we’re doing it. This is a graphic representation of the heart. And this is the right side of the heart, and this upper chamber is called the “right atrium.” This is the left side of the heart and this upper chamber is called the “left atrium.”

Now when we’re in our mother’s uterus, in utero, there’s a connection here between the right side of the heart and the left side of the heart, and this little tunnel here is called the “patent foramen ovale” that all of us have when we’re in our mother’s uterus. And the reason for that is that the baby inside the mother’s uterus does not breathe, and so the blood does not go to the lungs. The mother’s oxygenated blood goes from the right side to the left side of the heart, and then the left side pumps the blood to the rest of the baby’s body.

As soon as we’re born this PFO closes in most of us over the next one to two years. In 75% of us this patent foramen ovale or this tunnel will close. In 25% of us this patent foramen ovale will stay open for the rest of our life. So why does that even matter? Well it matters because in some people we may develop little clots inside of our legs in the valves, and if they come up and there’s no connection, they go to the lungs and nothing happens.

If this small clot comes up to the right side and can get across this patent foramen ovale into the left side, that can be a cause of a stroke because that small clot can then travel through the left side of the heart, get pumped up to the brain, and cause an injury in the brain which is a stroke. And here is a diagrammatic representation of a small
clot that comes through the right side, can get through that PFO, and then the left side pumps it up to the brain and causes a stroke.

What I’d like to do now is to show you a video, our first video that’s going to show a graphic representation of the PFO and how the blood can go from one side of the heart. Here is the picture of what I’ve just showed, and here is normally what happens, the blood, the darker, stays on the right side, the red blood is on the left side. Here’s the PFO. You see a little bit of blood that can go from the right side of the heart to the left side of the heart, and if a small clot forms in our leg, as we’re going to show you right here, in the valves in our legs, in the veins, there can be a little bit of sludging of flow if we get a small clot, even the size of the head of a pin. As it travels up, as we’re showing here, to the veins in our body and then can cross that PFO, go up into the brain, that can cause a stroke, and that’s the reason we’re here today, so that we can close this PFO.

Here is a representation of what Dr. Quesada is going to do through a vein in the leg, insert a catheter or plastic tube, and go up into the heart and fix that PFO. Ramon, where are you now in the Cath Lab?

Okay. Welcome back. So here we have two introducers, one in the right femoral vein, that’s a big vein, and another one in the right femoral artery. There is a catheter that I – can you show the fluoro images, please. There is a catheter inside the heart, as you can see there, that is an ultrasound, and with that ultrasound I’m looking at the heart. Can you show the ICE images, please. So there, as Dr. Machado will tell you, are the chambers of the heart where the defect is. Ralph, can you go ahead, please.

We’re going to label the chambers of the heart, right atrium, left atrium, this small membrane that you see is the interatrial septum. And I’d like you folks to keep your attention focused in the area designated by the arrow; that’s the site of the PFO. Dr. Quesada is going to inject a small amount of agitated saline in an attempt to demonstrate how bubbles may cross from the right atrium into the left atrium similar – in a similar manner that a small thrombus would cross creating that stroke. Ramon.

Yes. Thank you, Ralph. So you can see here I have another catheter in the – in the vein and we’re going to do what we call a bubble study. So I’m making little bubbles of agitated saline and I’m going to inject this to see if they cross in from the right side to the left side of the heart. Can you please focus in the ICE. You can see the injection here of the bubbles.

You need a more vigorous injection, Ramon.

We need a more vigorous injection. So what we’re going to do is I am going to get more fluids and I’m going to pull this catheter out to do a good bubble study. Can you hold this thing for me here. Thank you. Give me the syringe. So we’re going to get more bubbles. All right. Same procedure here, you can see it. And now we’re going to do a real injection. You can see the amount of bubbles crossing from the right side to the left side. You see all those little bubbles, and that’s why this patient had two strokes.

Show the clip.

So can you play it back so they can see how the bubbles go.

Did we have another clip where the bubble study was better?

Yeah.

We’ll show you in a second, the first clip that we did. So, anyway, also by Doppler you can see – focus on the ICE, focus in the ICE, please. This is a study that we did just seconds ago – minutes ago before we went live. To prove the points, you can see the bubbles coming from the right side of the heart and top going into an inferior portion of this image, which is the left side of the heart, which is the left atrium, and proving that there is a communication between both sides. Ralph, you want to say something there?

No. Again, the same way that these bubbles are going across, a small thrombus would go across, creating a stroke.
So the next part of the procedure is we need to put our catheter across that tunnel so we can go ahead and advance our devices and close it. So before we show you that, let me just advance the catheter with a wire inside the right side of the heart and then across the tunnel. Okay. All right. So you see – can you show the fluoroscopy images, please. So as you see the catheter inside the heart in the right side, so I’m pulling back the catheter, you can see it right here. And I’m guiding myself by the ICE images and also the fluoroscopy images, and I cross through the hole into the left side of the heart.

Now we usually like to be in a place that we call the “pulmonary vein,” and we’re going to make sure that we are there by echo imaging. Can you show me if I’m there, please. I believe I’m there. Yes, I think I’m there. Put some color there. So that way the patient at this point is having – we have already given anesthesia in the pulmonary vein or in the left atrial appendage.

Color off, please.

So we are always are very careful to where we position our wires so we don’t have any chances of putting the wire in a place that we don’t want to be. So we want to be in the left pulmonary vein.

I’m not seeing the veins real clearly.

Okay. I’m there right there.

Okay. There you go. Okay. You’re good.

I’m good. So, anyway, so we leave the wire there. Can you show me the fluoro, please?

That’s nice.

I’m going to leave the wire there and we’re going to pull it out.

You may be in the appendage there.

I know. It’s all there.

Okay.

All right. So the next step that we’re going to show you is the devices before we go back to Dr. Roberts, then we’ll explain to you how do we do this. Can the cameras come over here. So we have different catheters that we use. First of all, we’re going to measure the length of the tunnel that we’re going to close, and for that we use a balloon, which is here. And we’ll advance this through the – we’re going to exchange wires. We put an introducer there to put a big balloon through that, and then we’ll see that in a second.

Can you put color in that images to let me see if I’m in the appendage on the left atrium. Appendage? All right. Can I have the multi-purpose. We’re going to reposition our wire in another place to make the procedure safer. It’s important. Safety is the essence of all these procedures. If there’s any questions, you just click through the internet, and we’ll be more than happy to answer and discuss it. So I’m doing the same thing, I’m in the left side of the heart. ICE – fluoroscopy, please. Yes?

I’ll just read some, and if you need to work or want to talk, just interrupt, please.

A great question, “I’m 70 years old and had a stroke last year. I have diabetes and high blood pressure. Should I ask my doctor to look for a PFO?” That’s a great question.

It’s a great question.

My answer would be if you have reasons to have a stroke, high blood pressure, diabetes, and especially if they’re uncontrolled, that’s reason enough to have a stroke, especially in someone who’s not young like this patient, 28 or 29 years old, and I would say, no, you do not need to. It’s the cryptogenic stroke that Ramon was talking about,
that means a stroke of unknown cause, somebody that has no reason, no diabetes, no hypertension, as in this young patient, that’s the ones that it’s imperative, I think, to look for a PFO. What do you think, Ramon?

I totally agree with you. I think, you know, all these patients that we are closing, they go through a very thorough neurological workup. That means that their neurologist have evaluated and looked for other all possible causes of stroke, and the only possible cause was this, and it was diagnosed. So in a patient like the ones that you asked the question, a 70-year-old patient with diabetes, hypertension, those are all the reasons why this patient could have a stroke.

Ramon, what are some of those other tests that you get for your patients if they came in with a stroke that would be ordered to look for cause of a stroke?

Well, the first thing that we do is the first set the etiology of the stroke. Is this stroke embolic, thrombotic, hemorrhagic, so they do MRls and CTs of the brain. We do carotid studies because the carotid in these elderly patients are a source of embolization, and also arrhythmias in the heart, arrhythmias in the heart like atrial fibrillation with irregularities of the heart. See, you can have bad ventricles also after your heart attack. Those are sources of possible emboli. So we do a very thorough workup.

As a matter of fact, we will not close a patent foramen ovale unless the patient has full evaluation by neurology and also a full evaluation or a hematological profile making sure that there’s nothing else that could explain this.

I think it’s so important, what you just said. If there’s another cause of a stroke, someone has an irregular heart, as you mentioned, atrial fibrillation, if you put a PFO closure device in, you’re not treating the cause of the stroke. So, as Dr. Quesada mentioned, you have to have a complete evaluation for the stroke that includes your neurologist, a cardiologist, and I want to stress that. I think it's important. Okay. Shall we take another question or, Ramon, do you have – where are you in the procedure?

We are right now advancing a balloon across the device.

Okay.

Across the – not the device, across the defect in the septum, and you can see it here. Show the image in fluoroscopy, you can see that catheter go, those two markers there; that is a balloon, and we’re going to inflate the balloon slowly to see the defect in the middle. You can see it there.

Now what’s the purpose of inflating the balloon? What are you looking for?

We are looking for measuring – most done measuring the size of the defect, looking at the anatomy of the tunnel. The anatomy of the tunnel is important because sometimes we have to select the proper technique and the proper device to close this defect. So right now we are measuring this. We took a picture. I will measure the size. And this is a small tunnel, as you can see here, a straight tunnel, a straight channel with no significant problems. Some tunnels can be very tortuous and long and that (INAUDIBLE) has to do a different – take different approaches and different techniques. Sometimes we have to go through the septum with a needle if the tunnel is too long and close it from both sides. So it’s technical aspects that we have to make sure. So we learn a lot about the anatomy of the tunnel by doing this balloon sizing.

Okay.

We already saw that and we’re going to pull back with our balloon. And, Ralph, do you want to comment on the echo that we saw with the balloon.

Well, what Dr. Quesada has done is he’s inflated the balloon to the point where the color flow stops, and once the flow stops, that balloon is filling the tunnel, giving us clear images of what that tunnel really looks like, how wide it is, how long it is, and we’re able to judge what type of device, as well as how large the device needs to be placed.

So now we have an idea. We think that the device is about 1.1 millimeters – 10 millimeters. And we’re going to choose different devices to close it. Let me show you – can you focus here for a second.
Ramon, you said about 10 millimeters, how many inches is that for our viewers that don’t understand millimeters?

Half inch.

Half inch.

Half inch. So this is a catheter that we call the delivery sheath. So our device is going to go through this catheter, and we’re going to mount it. And this is the device that we’re going to use, it’s called the “Cribriform device.” Dr. Roberts will show you in a minute how this works in the cartoons. And we attach this umbrella-type of device to the catheter that’s actually going to deliver it, and we mount it. I tend to drop these things, so anyway. But I did it right this time. So the device is mounted.

Can they do a close-up of the device and then, Ramon, can you pull it apart to see the two discs?

Yes.

Is that a possibility?

Can you show it? It’s a close view? Are you seeing a close view of this? So I’m pulling it apart right now. You see it?

Perfect. I see the two discs and a little waist in between the two discs. Okay. So that’s the closure device.

So I mount it. Let me do it again. You want me to do it again?

No. No. No, we see it. Do your normal procedure.

Okay. So now we’re going to mount the device inside the catheter and we do it under water so there’s no bubbles there, because bubbles can also be a source of embolic events into the brain. Can you focus on this for a second, please. So we’re putting the device inside the catheter to deliver it and then we flush it. Very good. So we’re flushing this under water to get rid of all the bubbles, as you can see here. So the bubbles are going out, there’s micro bubbles, big bubbles, little bubbles. So we take our time.

This is a very important phase of the whole procedure. You want to make sure that it’s clean, that there’s nothing, there’s no bubbles inside the catheter. Once we have that, the catheter is ready to be placed into the delivery sheath. Okay. So we leave it up for a little bit here. And we’re going to go and now place the delivery sheath inside across the left atrium.

Ramon, while you’re doing the delivery sheath, I want them to stay on you and watch. Go ahead.

Okay.

A great question here from a viewer: “Aside from stroke, what other symptoms would a person experience if they had a PFO, and does the PFO cause a heart murmur?”

That’s a great question.

It is a great question. There’s no heart murmur. We do not hear – if you have a murmur it’s not from a PFO. And Ramon, do you want to talk – are there any other symptoms other than having a stroke?

Oh, yes. You know, as a matter of fact, we have seen everything from a PFO. Remember, this emboli is very common to go into the brain because the arteries from the brain are the straight shot from the heart, but it actually can go anywhere in the body, can go to the legs, can go to the kidneys, can go everywhere. You even can have paradoxical embolization to the arteries of the heart and have a heart attack, and that’s uncommon, but it happens. So any place that the arterial circulation goes can be a source of an embolization from this defect.

Great answer. Where are you now? Do you have the delivery sheath in or are you placing it in?
I am placing it in and I have the wire across. Can you focus right now on my hands, please. Right here, show my hands for a second. We are advancing the sheath inside the femoral vein and I’m going to show you, as Dr. Roberts showed you in the cartoon, how this happens. So this is the catheter and it’s going up to the heart.

And you have a guide wire already in the left side of the heart coming out in the vein and the leg, is that correct?

Yes.

Good. And you’re just advancing that sheath --

Are you seeing the fluoroscopy?

We are seeing it great.

So, okay, hold the wire. Put down – let me do this. So let me show you this. Hold the wire. Hold the wire. Hold the wire. Now I am getting inside the heart. I’m crossing the defect. And the wire came back a little bit. Thank you.

You lost image, Ramon.

I lost image? See the fluoroscopy, please. I am there. So the delivery sheath is inside the heart. And now what we’re going to do is we’re going to leave the delivery sheath inside the left atrium, as you showed in the cartoon, and we’re going to pull the delivery – the introducer, leaving the wire for a second. Do it.

For those of you who may just be joining us, welcome to Baptist Cardiac and Vascular Institute. If you have questions, there’s a little button you can press on your screen, just ask a question. We’ve gotten some great questions from our viewers.

So now we put in the wire, and we’re going to clear the catheter of any bubbles that are possibly there. So we don’t want any embolization. That’s what I’m doing right now. Can you focus on my hands, please. That’s exactly what I’m doing. And we’re going to be ready to deliver the device going inside the catheter. Look at my hands, please. Okay. Thank you very much. Flush. So this is the device mounted in this catheter, which I’m going to advance.

Ramon, before you deploy –

Yes. I’m going to stop.

Okay. We have these great graphics, I just want to go over something.

Yes, I’m just going to show you where the catheter is at the tip and then – right there. You can go in and do your thing.

Good. Let me show everybody a little graphic representation of what Dr. Quesada has just done so you have a good understanding. Here, again, is this picture of the heart, and what Dr. Quesada has done is he’s placed this plastic hollow, we call it a “delivery sheath,” across the patent foramen ovale, you see right here, into the left atrium. And this is a blowup view. It’s a hollow tube, and through this hollow tube is where the delivery is going to take place of the closure device. Okay. So that’s what –

You can see that echocardiographically as well, Jonathan, right now.

Great. I’d love to see that. Why don’t we show a clip. We have our second clip that will show a video animation of closure of the device. So here’s showing the catheter, what Dr. Quesada has just done. The catheter is across the interatrial septum, across the PFO. Here’s one disc being deployed in the left atrium. And then Dr. Quesada will pull that tense against the left atrium, expand the disc in the right atrium, unscrew the device, and it stays there and that seals off the PFO. Great.

Okay. So, Ralph, you want to show them -- show the ICE image, please.
Remember before, this was the left atrium, right atrium on top. Here’s the catheter going through the PFO into the left side of the heart, and through that catheter Dr. Quesada will deploy his device. Again, just keep your attention focused in the area of attention where the arrow points.

So let’s go through fluoro light for a second. So now I’m advancing the device and pulling the disc, as you can see here. Can you show the – this is the disc in the left atrium. And now show the disc in the ultrasound, please. You can see perfectly the disc in the ultra – in the IVIS – in the ICE. And now we’re going to pull down to the septum to deploy the other sides of the device. So you see it coming down to the septum, you see it right there, opposing the left side of the device against the tunnel in the left atrium, and I’m going to start developing -- pulling the right disc of the device like so, and now I capture the septum on both sides of the device. You can see that right there. And then we stay. We take a break. We make sure that everything is the way we like it before releasing the device.

Ramon, while you’re taking a break and watching that device, we had some great questions. I just want to ask you some of your thoughts. Question: “Would you say that the PFO is benign in most people that have it?”

Absolutely. 20% -- 15 to 20% of adult population have patent foramen ovale, and they never have a symptom in their life. It’s a very few percentage of patients, of population, that can have this event. So having a PFO is not a disease, it’s a variant, I can say. And we only treat them when it is really necessary. Let’s say you are a pilot or you are a professional diver, a marine biologist and you’re going to go deep in the ocean, and regardless if you have foramen ovale, the risk of embolization are higher, and then in those are situations in which we would close it. But other than that, you have to have evidence of pathological event. That’s what we would call it.

I think that’s really important to stress that, again, in some series up to 25% of patients will have a PFO. That means 70- or 80-million Americans are walking around with a PFO. Most people, in the vast majority, it’s totally benign. So you don’t need to seek out and worry about it.

All right. You want another question, or do you want to keep going there, Ramon?

Another question would be good.

Okay. This is a great question. “I’ve heard of a PFO with an atrial septal aneurysm. What does that mean? Is this worse than a regular PFO?”

Well you know that’s a very important question. Actually, that’s an incredible question, because, really, atrial septal aneurysm, it means that the septum is very floppy. Like this in particular patient, maybe we didn’t say that at the beginning. This patient has a very floppy septum. It’s like an aneurysm. Either the septum is not straight, it moves with the movements of the heart inside the left atrium and then back into the right atrium. The association of an atrial septal aneurysm or a hyper modal septum is considered that in the presence of patients for foramen ovale increases the chances of having a shunt embolization. But the atrial septal aneurysm by itself, without evidence of communication, is not really associated with pathology at this point.

I’d like to just comment. Usually when we think of an aneurysm, especially in the brain or in the aorta, we’re talking about a swelling of a blood vessel that’s abnormally dilated, and really an atrial septal aneurysm is not that. We’re not talking about that. And I think I wish it was never called an aneurysm but was called a floppy septum, just what you said. And it’s not a vessel that’s going to burst open. That’s a little bit of a -- a lot of our patients when they hear “aneurysm,” there’s a lot of fear that something’s going to break. Any comments about that, Ramon?

No, I totally agree with you. I think it’s a misname of the aneurysm. It’s not an aneurysm. It’s a floppy septum. It means the septum moves too much. But nothing is going to happen if there’s no communication.

One more question. This is a really good question. “What are the risks associated with this procedures?”

Well, fortunately, this is a very safe procedure, but it’s an invasive procedure. Any invasive procedure carries the risk of bleeding, even perforation of the heart because we’re putting tubes and catheters inside the heart with wires. You saw me moving the wire from one position to the next position, and I mentioned the word “safety”
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because it was in a place that is called “atrial appendage.” It is a very thin structure that is very easy to perforate. So you have to be very compulsive and very careful when you’re manipulating wires and catheters inside the heart. So even though it’s a low-risk procedure, it’s considered to have possible complications. That’s why when we do these procedures you have to make sure that the patient needs the procedure to be done. So indication is very, very important. So this is not -- that’s why we don’t close everybody, number one. This is an invasive procedure and needs respect of being an invasive procedure.

One more question, then I want to see you release that disc. Somebody asks, “Is there any other therapy for a patient with a stroke with a PFO, and is it as good as a closure device?” That is a very, very good question. Yes, there are other therapies available for patients with stroke, and one is the use of anti-platelet therapy, and the use of anti-coagulation with Coumadin. That is compatible as using closure. The difference is -- and there’s a study that was just presented a year ago. We were part of the study called a “Closure trial,” in which we compared patients with TIAs or strokes, more than one stroke, to continue on medical therapy with Coumadin or anti-coagulant therapy with aspirin, Coumadin or aspirin, versus closing the defect. And the surprise was that both groups did equally. The incidents of second strokes after two years was very, very similar. So there was no advantage.

But that doesn’t mean that the study was negative. What it means is that medical therapies are very efficacious, but you have to continue with the medical therapy. So patient who are already on Coumadin who are young patients, like this patient is 29 years old, if we don’t close this defect -- you already have two strokes -- she needs to be on anti-coagulation for the rest of her life, and that is really what the difference is, is the choice. Do we close it, because otherwise you might have to be on anti-coagulants for the rest of your life, which is a very good option, by the way. That’s the way it was done.

In the past before we had the PFO approach and patients had recurrent strokes or embolization because of PFO, the surgical option was done. The patient was operated because of that. So that’s extreme today but it was done. So we have to put the things into balance and individualize for each patient in particular.

That’s a great answer. And the closure trial that you’re talking about really has made it a little bit either easier or more difficult when we talk to our patients, as, Ramon, you said, really the two-year follow up of these patients randomized to medical therapy or closure with the device, the recurrent stroke rate was very low and about the same in both, and this is an area in medicine we don’t have a 100% answer all the time, and this the patients in this study -- Ramon, you can address this if you like -- did not have to have brain imaging or a stroke or showing something happened in the brain. It’s certainly not the patient that you’re closing right now, someone that’s had past strokes and comes in with a present stroke. So I think we need to do a lot more research.

There’s two more trials going on, comparing the device closure of medical therapy, and this is a great area that we need to explore more, and I’m really glad here at BCVI, Baptist Cardiac and Vascular Institute, we’re involved in this to try to help further the science of strokes and treating PFOs.

You know, I think that is very, very important. And as you mentioned that in reality and as an investigator in the trial, you know, most of the patients were referred for us for the trial, we couldn’t even randomize it. It took us eight years to finish the study, and the reason was because patients had already a serious event. They didn’t want to be randomized. They wanted the defect to be closed. So at the end, we end up randomizing patients that were probably low risk. And the other thing, that there was no really strict documentation of a neurological event, which means by MRIs or different tests proving that there was a real event. It was a clinical interpretation of a trans-ischemic event, which is very subjective.

In our own practice today, we really don’t close defects by our clinical judgment. These patients are referred after a very thorough neurological workup, and it’s really the neurologist who tell us this patient needs to be closed, and then we, as an interventional cardiologist, go ahead and make the assessment in closing and if it is suitable for closure. But in reality, the indication is really after a very, very thorough neurological workup and individualizing every patient by itself. If a patient is a high risk because he’s open -- like this patient, this patient had a floppy septum. She had a wide open patent foramen ovale. The bubbles cross very easily from one side to the other side. She already have two events, and she’s 29 years old, so what are you going to do?
That's the patient. What we're going to do is what you're doing today, is closing the PFO, the defect there. Ramon, I want to make sure time-wise we have enough time. Can you go ahead and let's move along and deliver the device. Show us how stable it is by pushing and pulling, and then show us the delivery of the device.

Okay. Can you show, please, the ICE imaging. So you can see here the image in the ICE, it's a disc, you have two discs. One side on the left side, where the arrow is, it's on the right side. And this is the arrow on the left side, and now the other disc is on the right side, and in the middle of that is the septum, and you see the floppy septum moving on your left, and you see the tunnel, and now we need to test that the device will stay there. In other words, I don't want to release this device and it will slide around the heart somewhere else. So we make sure that the device is stable. So for that we do what we call the "tugging maneuver," which is we pull back and forth, making sure -- you can see on the fluoroscope that I am pulling the device back and forth making sure it is stable, and it is stable. So I'm very comfortable that the device is in good position.

Can you put color flow to see if there is any flow around? Now, remember, this device is not released, so some tension on the septum, and you can see flow inside the device. So I am happy. It's compromising any structure, and now we're ready to release it. You can see the fluoro image, please.

Before you release it, let's watch that video one more time.

Yes.

So people will understand really in their mind what you're doing. So, again, this is showing the catheter going across the PFO, and here is the release of the left atrial disc. And as you saw Dr. Quesada do, you pull it against the inner atrial septum like that, and then we saw the second disc, the right atrial disc deployed, and then right now what Dr. Quesada is going to do is unscrew that device and release it so that it's closing the PFO. Okay, Ramon.

All right. Let's go to the fluoro for a second. You see the fluoro, I'm putting -- see it in there. And now I'm turning this. You can show my hands if you want to. And we're going to release it. The device is released. And now we're going to go back to -- let's go back to the ICE imaging, please.

You're just imaging on the ICE right now?

Yes. I'm going to include the image on the ICE. All right. You want to comment, Ralph.

Here you see the device released in its final position. It acquires a better position once it's released from the catheter, with the left atrial disc and the right atrial disc in an appropriate place, closing the PFO channel.

So now we're going to do a bubble study again. The other thing that we always do is we check around to make sure that we're not compromising any structure of the heart that we already did before we released anyway. We always do it twice to make sure that everything is fine. I'm very happy with the result. It's a spectacular result. It really is. And now we're going to repeat a bubble study, you know.

Ramon, while you're getting that ready, here's a question. "Does this procedure carry a risk of stroke itself?"

Absolutely. There's no question about it. We are having catheters inside the heart, and you can form clots on both sides of the device, and that's why these patients are with blood thinners. We put them on heparin. Heparin is an intravenous blood thinner through the device and we test the blood to make sure that the patient is well anticoagulated through the procedure.

And is there someone that you would not close a PFO that you thought that was the cause of their stroke because of a clot somewhere.

If the patient had a clot the left ventricle or had a clot on the left atrial appendage, then it's a difficult procedure because you're going to be manipulating the device inside the left side the heart, and then you don't know if it's the left atrial appendage with a clot inside their heart or the left ventricle, the apex of the heart with a clot, another PFO, so you have to be certain that this is the real reason why we are here.
So I’m going to do another bubble study. Please look at the ICE.

If I could make a comment. Sometimes -- most of the time this bubble study is negative; that is, bubbles no longer cross. But it isn’t necessarily the case in all patients. Oftentimes it takes six weeks for the device itself to epitheliize and seal in a more permanent way.

I totally agree with you. I think, you know, even if we took a couple of bubbles crossing through, I’m not worried about it, because, as you mentioned, this is going to close. There’s always nice to see that there’s no bubbles going through. So let’s see now. Can you show the ICE imaging please. You can see that compared to what we had before, there is no bubbles going through, so this is a perfect closure, great result, and we are happy for the patient.

Ramon, if you saw bubbles still, would that concern you, and how would you follow this up?

Well it wouldn’t concern me, really. Because, as you know, because of the texture of the device, you could expect to see bubbles immediately afterwards. We would follow this patient with a transthoracic -- in bubble study, repeat bubble study in a month and three months, to make sure everything is covered and totalized.

So and the other thing that we do is that we keep these patients on the anti-platelet therapy, aspirin, and Plavix, which is another anti-platelet drug, for three months until we’re certain. It varies three to six months. It depends. And the study we were mandated to keep them on aspirin forever, and Plavix up to three months until we’re sure that the whole septum is covered with tissue.

Another question I think is great, “Is general anesthesia used for the procedure, and can you explain what the recovery is like and how long you’re in the hospital after the procedure?”

This patient is sedated. It’s what we call “conscious sedation.” We make her comfortable, but she’s not under general anesthesia. In babies they use general anesthesia because -- obviously. And if I were to intra transesophageal, also sonography, put a catheter in the esophagus, those patients, we put them under anesthesia. But we use mostly for this type of procedure intracardiac ultrasound. As you can see here. Can you show my hands for a second, please.

This catheter here is the ultrasound, and this catheter is put into the heart so I don’t need to do any anesthesia. We pull the catheters out as soon as we finish, and these patients stay in the hospital for 23 hours, and they go home. It’s an outpatient procedure basically.

So they go home with a band-aid in the groin where you made the puncture site, is that correct?

Absolutely. Correct.

And they’re up walking around several hours after the procedure?

They get up after four hours, four hours after the procedure.

And what restrictions do they have after they go home? Well the only thing -- the important thing is that they should not go and do heavy-duty sport because the groin is going to be a little bit tender, and they can have a hematoma. Other than that, they’re not restricted. I don’t -- well their restriction is if they do like diving, any sport like that, we would like them to stay away from that for at least three months until we’re certain that everything is closed.

And again, any special medicines that they go home on?

They go home only on aspirin and Plavix, and apply it for a short time, and baby aspirin indefinitely, and antibiotic prophylaxis. What does that mean? It means that you have a device inside your heart, so if you go to the dentist and have dental work, for the next six months, until we are certain that this is covered by tissue to prevent the risk of infection -- and I haven’t seen one, thank God, yet, we give them antibiotic prophylaxis for dental procedures or colonoscopies, any procedure that is not considered to be a clean procedure.
And if the patient came in on Coumadin, as many of our patients do that have had a stroke, and we find a PFO, what do you do then?

We take them off Coumadin, and they go off on (INAUDIBLE), unless there is an indication for Coumadin for another reason. Let’s say the patient has atrial fibrillation, then this patient probably should be on Coumadin, and this patient should continue on Coumadin. Just put them back on Coumadin and a baby aspirin.

Okay. A quick comment regarding the anesthesia, Ramon. These patients are under deep sedation, and it’s a type of anesthesia similar to what one might receive for a colonoscopy, for example, where you’re asleep. You don’t remember any part of the procedure usually, but awake and really ready top go in a relatively short order.

Thank you, Ralph. I should have let you answer that question about anesthesia first.

Yeah. Another question here, Ramon. "What is the expectant lifetime of this device? Does this cure the PFO forever? Do you need to replace the device in the future?"

First of all, this device is going to be part of your body indefinite, for the rest of your life. Now saying that, there are two new devices that are bioabsorbable. They’re not approved in the United States. They’re only investigational. One is made out of pig intestinal mucosa that is approved for plastic surgery. They use it in burn patients. So instead of having the disc, they have discovered that it is biodegradable. And there’s another device that is totally experimental also, but it’s completely a hundred percent bioabsorbable, so the device will disappear with time, in approximately six months to a year. But those are not approved. They’re far away from being in clinical trials in the U.S.

And the other part of the question was? Oh, to replace it? No, they’re not going to be replaced. Sometimes what happens is that you can miss another defect. You shouldn’t, but occasionally that could happen and then you have to come back and enclose it with a second device. But that is rare. And in about 90% in the closure trial, using not this device, other device, there was 85% of closure rate, less than 90%. What does that mean? That means that there was a lot of patients, about 10% of patients, that still have a mini chance after follow up. That is very -- it’s specific to the device that was used, but I think with the new generation of new devices that is very rare.

Ramon, let me ask you a question, and this is going to be a little bit -- it’s real day-to-day life. A 55-year-old diabetic has a small stroke, recovers thankfully, and in the workup is found to have a PFO, and his neurologist tells him, "Don't worry about that. Let's control your blood pressure, your diabetes, and we're going to put you on aspirin." What are your thoughts about that?

Well, you know, age was not -- it didn't make a difference. It's as common in young patients as in elderly patients. But if the workup was completely negative and it's an insignificant PFO, I will treat it with medical therapy. There's nothing wrong with medical therapy. It's really until we have sort of data, I think we have to consider medical therapy also as a first option.

I think that’s a great answer, that we’re in a time period where we’re not certain always what the right answer is, and I think there’s two good therapies, medical therapy and device closure. This patient, though, that you showed us is just a classic patient that I would close the PFO. A young patient that's had prior strokes and present stroke, and are they going to stay on Coumadin for another 50 years. I agree with you that this is a patient that we should close the PFO, the one that you have on the table.

Absolutely. I think this is really -- that's why we want to show this because there's a lot of information in the press about all these things, and, really, you know, doctors try to do the best for the patient, and every patient needs to be individualized. Treatments cannot be generalized. So sometimes too much information is not so good.

Yeah.

So if you have a problem and you have a question, it’s better you discuss it with your doctor, because he or she will look at what is best for you. And that’s what we try to do.
Another good question: “Can this procedure be done through the arm, or does the catheter need to go through the groin?”

That’s a very good question.

We have some smart people out in the audience there.

Right. I know. Most of the time, this procedure in particular is done through the groin. It’s easier. Now saying that, we have done this procedure when there’s no access from the groin because there’s problems in the venous system, through the neck, a vein in the neck. But that’s unusual. From the arm, even though there’s a couple case de described in the literature, that is not the usual and the standard of -- not only that, you have to use a really, really, really long -- not long -- a large sheathe. The risk, forget about it. The risk is too small.

I think what the viewer may have been thinking about, because there has been a lot of press recently in the Miami Herald, is that we’re doing cardiac catheterization in the artery to go up to the coronary artery to the radial artery.

Right.

Which is in the wrist and, that’s through an artery. And to close the PFO, we have to go through a vein, and we just don’t have the same access in the wrist that we do for a vein as we do in the groin or in the neck, as you mentioned.

Absolutely. It’s a totally different procedure.

Another good question here: "Will I feel the device once it is in place?"

No, you will not feel the device. But saying that, because it’s a device, like it’s a foreign body in your heart, in the first few weeks there is about 5% instance that you can have palpitation, extra beats, originated in the atrium because you have the device. But it’s usually transient and will go away. But no pain or anything like that.

Yeah, I think that’s an important answer. Really, you can’t feel it, and except for the transient atrial, these extra heartbeats, it’s really amazing.

It’s amazing. You go back to your normal life. And most important, you feel comfortable that you’re not going to have other problems. You know, it’s interesting, nobody asked the question about migraines and --

That was the next question. I have it right here.

Okay.

A patient said, “I’ve heard that PFO closure can cure migraines, is that true?”

Well this is a very important question, because in reality there is an association. There’s been an association between migraines and PFO. But we’re interventional cardiologists. First of all, we don’t know the physiology of the migraine headaches, and you know, but it’s a lot of saying, there’s a theory that is also that is also micro embolization or vasoactive substance that is not active in lungs that is go into the brain. But let me tell you some facts. The only study that has been randomized, it was a European study, it showed no difference in migraines.

Even though the incidents of migraine attacks were lower, the study was considered negative.

Now on the other hand, all these things with migraine started because all of us were doing PFO closure, and in our own series more than 400 patients who had PFO closure for strokes, or really, embolization, 30% of those patients had migraine headaches associated. And when we followed these patients, even in our own series, these are not randomized trials, this is only observational in close to 90% of those patients, the migraines went away. And because of that, in that same experience, it has repeated in multiple sites, operators doing these procedures, the whole theory of the migraines and PFO closure came about. But in reality we don’t have any proof of that.
And in the era of evidence-based medicine we have to prove effectiveness of therapy before we can just say, “Okay, let’s close it.” So we don’t close patients for migraines. We close patients like this patient, for stroke. I don’t know, what do you think Jonathan?

Ramon, I really agree with what you say. I think there’s going to be a segment of patients with migraines that if we close the PFO it will make them get better, because patients that you and I have closed, some of them say it’s just incredible. They don’t care that they’re not going to have a stroke. They love it that they don’t have a migraine. We also have some patients that I close there PFO and I see them in follow up, and now they have headaches, and that’s the rare patient. I think there’s so much we need to know. We need to continue the research that we’re doing here at BCVI and that’s being done throughout the world so we can figure out who those patients are that we could help.

We’re just about out of time, and I want to remind our viewers that if you missed part of this, if you came in late or if you’d like to watch it again, it will be available at BAPTISTHEALTH.NET, or you can go on OR-LIVE.COM and you can find the site and view it again for your viewing pleasure and to learn more about this. I’d like to thank Dr. Rafael Mashado [PH] of anesthesia who joined us, of course, Dr. Ramon Quesada, and thank his patient who agreed to do this, and thank all of you as viewers for coming and watching. We hope that you’ve learned something. We hope that you enjoyed the presentation.

I think we have time for one more question or comment. Ramon, anything else that you want to say to the viewers about PFO closure and about the patient that you just did?

First of all, I want to thank everybody for being with us for an hour. It’s been really a pleasure. We’re very passionate about our work and what we do here at BCVI. And I want to thank my team for being with us late today doing this procedure, and it really is all about our patients. It really is all about doing things that will help them have a normal life.

And I encourage you to talk to your doctors if you have any problems. And what you see in the press, most of the time it’s not the actual facts, so get the right information from your doctors. And I want to thank you again for being with us. I want to thank my team, and have a nice evening, morning, or afternoon wherever you are. Thank you.

Good. Thanks again for joining us here at Baptist Cardiac and Vascular Institute. Again, if you missed this or want to view it again, we encourage you to go to BAPTISTHEALTH.NET or to OR-LIVE.COM, and you can find the on-demand button to watch this again. Any other final questions that we have that we can fit in here? And do we have anything there? I think we have about one more minute.

Oh, this is a good one. “Why does the foramen ovale stay open in some adults? Is it just genetics or is it just something developmental, and why does it close in others? Ramon, any thoughts on that one?

Yeah, that’s a very good question. You know, because it’s difference of pressure. It’s a tunnel, it’s not a hole. First of all, it’s a tunnel. So when you’re born and you take the first breath, the pressures in the right side of the heart drop, so the tunnel seals. But in about 15 to 20% of the normal population this can remain taken, meaning that if the pressure on the right side of the heart increased, it can open spontaneously.

Ramon, I’m sorry to interrupt. We’ve got the signal here that we have to wrap it up.

Okay.

Thanks everybody, for viewing we hope you enjoyed this. We hope you learned something. And all of us here at Baptist Cardiac and Vascular Institute, we thank you for joining us today. Have a good afternoon.

Thank you very much. Bye-bye.