

**ABDOMINAL AORTIC ANEURYSM
ST. LUKE'S EPISCOPAL HOSPITAL AND TEXAS HEART INSTITUTE
HOUSTON, TEXAS
December 5, 2007**

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ANNOUNCER: Welcome to St. Luke's Episcopal Hospital and Texas Heart Institute in Houston, Texas. Over the next hour, see treatment for an abdominal aortic aneurysm featuring the Gore Excluder AAA Endoprosthesis. If a rupture of an abdominal aortic aneurysm occurs, the person experiences severe pain in the back and/or abdomen and may become unconscious. Unless the leading aneurysm is surgically repaired immediately, death results. In just moments you'll see how the Gore Excluder AAA Endoprosthesis is used to internally reline the abdominal aorta and isolate the aneurysm from blood circulation. ORLive makes it easy for you to learn more. Just click on the "Request Information" button on your webcast screen and open the door to informed medical care. Now, let's go live to the operating room.

00:01:04

NEIL STRICKMAN, MD, FACP, FACC: Hi. Welcome. We're glad you're all here to watch a very exciting case we have of an endovascular treatment of an infrarenal abdominal aortic aneurysm. We're live here at the Texas Heart Institute in the St. Luke's Episcopal Hospital in Houston, Texas. I'd like to tell you that we have many people involved and that this is also being done in a cardiac catheterization laboratory instead of being done in a surgical OR where it normally is done. In the background [Acon?] and Mamma Latonya are helping us and I wanted to introduce now to Dr. Zvonimir Krajcer, who will headline the show.

00:01:40

ZVONIMIR KRAJCER, MD, FACC: Good afternoon. It's a pleasure to show you this interesting case from Texas Heart Institute, St. Luke's Episcopal Hospital here in the endovascular suite of our cardiac catheterization laboratories. With me here is Dr. James Livesay. He is cardiovascular surgeon at Texas Heart and St. Luke's Episcopal Hospital, and it's a pleasure to have him here. We're going to be working together doing this procedure of endoluminal repair of the abdominal aortic aneurysm with an Excluder stent graft. Next to me is Dr. Eduardo Hernandez and he's an interventional cardiologist also at our institution. And then new have Ed Minor, he's an interventional cardiology fellow rotating through the peripheral vascular service here at our institution. And Sam was already introduced earlier. He's going to be assisting us also during the procedure. We have an interesting case here that I will show it...like to show it to you. This lady is a seventy-four year old lady with an abdominal aortic aneurysm that has been diagnosed by a CAT Scan. It's five centimeters in diameter and it has been enlarging. It enlarged approximately a centimeter and a half in the last six months. She has multiple co-morbid conditions, which include arterial hypertension, coronary heart disease. She is status post-previous coronary bypass surgery. She also has chronic obstructive pulmonary disease and chronic renal insufficiency. And she was considered to be a high risk for surgical repair of her abdominal aortic aneurysm, and her physician and also the patient elected to have a stent graft procedure, which is nonsurgical repair of the aneurysm, which will be done now. Now, her spiral CT with contrast of the abdomen and pelvis, with 2.5 millimeter slice...slices that we can see here, show that her neck at the renal arteries is approximately twenty-two to twenty-four

millimeters in diameter. The lowest renal is the right renal artery that you have seen previously. And then further down the neck is the twenty-two millimeters, as you can see now, and that's approximately twenty-five millimeters below the origin of the right renal artery. And further down it's still twenty-one to twenty-two millimeters in diameter and then it gradually dilates further down. As you can see, it becomes aneurismal. And as I mentioned the maximum diameter of the aneurysm is five centimeters. Now the interesting feature is that you can see this on this particular slice that there is a flap or a tear or a dissection in the abdominal aortic aneurysm and we're not exactly sure whether this is a thrombus or actually a dissection that originated from a penetrating aortic ulcer. And there's also a thrombus in the aneurysm. Further down you can see the iliac arteries are between eleven to twelve millimeters in diameter. There is some tortuosity there as well. And then you can see the origin of the left and right internal iliac arteries. And the external iliacs measure approximately eight to nine millimeters in diameter. The last slides that you can see are the femoral arteries at the femoral head. And you can see that this lady is not obese. She's actually skinny, which we like, and there is not too much of space between the skin and the femoral arteries. And the femoral arteries measure 8.5 millimeters in diameter, which is very generous for a lady. And, I think this is going to simplify the procedure that we're doing now. Now, when we look at the CAT Scan measurement, which is absolutely necessary to get appropriate information about the aneurysm and whether the patient is a candidate for endoluminal repair, we can see that as far as the infrarenal aortic neck where actually we are going to anchor this device, is approximately twenty-four millimeters in diameter. The distal infrarenal neck is twenty-two millimeters in diameter and the infrarenal neck length is forty millimeters, which is a generous length. And maximum diameter, as we mentioned previously, is fifty millimeters, or five centimeters, and the iliac arteries measure between 11.2 and 12.3 millimeters in diameter. The distance from the right renal artery, which is the lower renal artery to the right internal iliac artery is 145 millimeters, or 14.5 centimeters.

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And this information is appropriate and adequate for us to choose the stent graft, which is going to be Excluder endograft. And the main body, or what we call the trunk ipsi device, will measure twenty-six millimeter in diameter below the renal arteries. And it will be fourteen centimeters long. And it's 14.5 millimeters in the distal diameter in the iliac arteries. This device will be deployed percutaneously by a right femoral artery approach. And the left iliac limb will be 14.5 millimeters in diameter and it will be twelve centimeters long. Now, as I mentioned previously, the procedure is going to be done via endoluminal repair with Excluder stent graft using percutaneous approach and local anesthesia. That means that we're not going to make any incisions and we're only going to use a local anesthesia in the groin area, very similar what is done during any cardiac interventional procedures or heart catheterization. The access was obtained using a local anesthesia with Zilocaine and a Micropuncture Kit, that is shown here, to gain access to both femoral arteries. And then we introduced 6 French sheaths bilaterally into the femoral arteries and performed the angiogram that you can see here, showing very long infrarenal neck. And there is a certain irregularity in this neck with the ulcerations. And if you concentrate you can see a flap there in the abdominal aneurysm that is moving with every heartbeat. And then you can see the tortuosity of both iliac arteries, but they are generous in diameter. Next one please. So the still frames show a little bit better that the right renal artery is lower. You can see some ulcerations in the neck and you can see that flap in the abdominal aortic aneurysm and see the iliac artery. So, at this stage I would actually like to ask Dr. Strickman to show you a demonstration of an angio, actually, which it's a...it's a demo of how the stent graft is being deployed. Neil?

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NEIL STRICKMAN, MD, FACP, FACC: Great. Thank you, Zvonimir. Let's go to the animation, for those of you in the audience. Now, again, we're presenting this for those

that are medical and nonmedical. If there are any questions throughout the procedure, there is an access button that...an access button that you can hit and you can send e-mail questions. So there was the ipsilateral limb that was deployed. This is, again, done by pulling a ripcord on the device and it deploys quite quickly. Now, during this part of the procedure the physician then gains entrance to the other side, called the contralateral side, via various techniques that we standardly use. Now this graft is quite unique. It has a Nitinol exoskeleton, the framework, with an EPTFE, very thin material but semiporous to allow adequate blood flow, but not allow leakage. Now here you can see the endograft that looks...sort of looks like a pair and a half of a trouser. This thing is fixed in the superior aspect by hooks that are on the top of the graft and that are sealed in by postdilatation with a balloon catheter. Now here you see the contralateral, or the opposite side limb that is deployed. And then at the end of the procedure you have an endograft that is hooked in underneath the renal arteries that goes to both the left and right legs so there is blood that is supplied to both legs. So at this point if there are any questions we...you can send them to us. Otherwise, we're going to go a head with the procedure. Okay?

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ZVONIMIR KRAJCER, MD, FACC: Thank you, Neil. Now I would like to show you what we have done so far. And we can go with the next slide, please. Again, I would like to mention that we are doing this procedure under a local anesthesia and percutaneous approach. And this is being done with a Prostar XL device, and we are using so called preclose technique. You can see here that this device is the suture media device that houses needles and sutures in it, and it's over the wire system. And if we can see the next slide you will see that this device can then advanced through the skin and subcutaneous tissues until you get to the arterial level. At that point – Next slide – you can see a blood return through little tubes that we call the marker lumen and this is the time, actually, to deploy the needles. That will be show in the next slide. And here you can see by pulling the pull rod we actually are pulling the needles. Next one. And you can see actually in this dramatic representation the needles are coming out, two in the front and two in the back through the anterior...arterial wall and entering into the barrel of the device. And then the needles can be pulled out and the sutures can be cut. Next one please. And here we can see now we have two sutures – two white sutures and two green sutures – and we use hemostats to mark them. And then the wire is introduced through a wire port into the Prostar XL device, and the device is removed. Next one, please. And the 18 French Sheath is introduced in this particular scenario in the right femoral artery, like we have done it. and the 12 French sheath will be...is introduced into the left femoral artery. The 18 French Sheath is used for trunks ipsi, or the main body of the stent graft, and the 12 French sheath is used for introduction and deployment of the iliac contralateral limb. Next one please. So, actually, I would like you to see what we have done so far. We have performed the angiogram. We already completed a preclosed technique. Here we have an 18 French sheath on the right side and 12 French sheath on the left side. On the left side we also have this 5 French renal double curved catheter, which we placed selectively into the right renal artery to mark the area of deployment of the infrarenal stent graft component. And, on the right side here, actually, you can see this main body of the stent graft. You can see it's a low profile device. And we are basically ready to advance it under fluoroscopy to the origin of the right renal artery. So, if you can follow this now, under fluoroscopy you can see that we are advancing the device. And, we can advance it all the way up to the catheter; renal double curve catheter that is placed into the right renal artery. At this point of time, we should pull...and we are pulling this 18 French sheath to...all the way to the white marker to make sure that the stent graft is actually now deployed in the sheath. And now we can recheck it. And, as a matter of fact, we could do a little test for you, or angiogram to see the origin of the right renal artery. You can test it Eduardo. Okay. So...go ahead. Okay. So we can take a little image, if you don't mind. Ready? Okay. Okay. So...so we can see now the origin of the right renal artery, and we can then get an image with bony landmarks and that's going to

help us quite a bit to mark that area. And we are currently marking this actual location on our screen so we can clear see it. And, I would say that we could advance the device just minimally up. Like this. And then we can pull our contralateral renal double curve catheter. And to this area.

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And we are ready, basically, to deploy the stent graft. And it will open up real fast, as you can see. Alrighty. So it's open fully, as you can appreciate it, and it's exactly in the area where we desire to have it placed. So now we can remove this deployment device and place a balloon that is going to dilate this segment of the infrarenal component of the Excluder stent graft. Neil, you are more than welcome to comment if you need to explain anything else in addition to what we have mentioned.

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NEIL STRICKMAN, MD, FACP, FACC: One thing we can say is the normal anatomy that we've learned that the two kidney arteries come off as left and right shoulder is really not true. Normally one is higher or lower than the other, and one is more posterior or anterior than the other. And your angiogram nicely demonstrates that the lower renal artery in this case was the right renal artery. And we like to place the graft as close as possible to the lowest renal artery so that we don't exclude one kidney once the stent graft is placed in.

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ZVONIMIR KRAJCER, MD, FACC: Alright. Very good. We could magnify it one mag up, so we can see it a little bit better while we're inflating the balloon. And we'll give a little bit upward push to make sure that we don't move the graft distally, because with every heartbeat there's a tendency for the graft to move distally. And we'll do it one more time to dilate it adequately, to approximate all the irregularities of this atheromatous aorta with ulcerations. We inflated...Unfortunately, you cannot see the pressure to the mean pressure when there is no really phasic flow. And, we also can ask the patient if the patient has discomfort. It's absolutely mandatory that you don't inflate it more than it's needed. And the patient can tell you if there is pain. Of course, this is done with local anesthesia and the patient is alert and cooperative. So now we're going to inflate this in the distal segment, or the iliac segment of the stent graft. And there is a little narrowing there, as you can appreciate it. I will go a little bit higher. Just a little bit higher pressure-wise. Yeah, you can go a little bit higher. Alright. That's good. And we'll pull it maybe down just a little bit more. Okay, one more time. Excellent.

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NEIL STRICKMAN, MD, FACP, FACC: Now when you're inflating, Dr. Krajcer, I notice that you're not using a device. You're only using a hand pressure. Is there a reason for that?

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ZVONIMIR KRAJCER, MD, FACC: Well, this is a very soft and compliant balloon. And normally, as you know, we like to look at the pressure, but I think in this particular scenario I don't think it's needed. We look at the pressures in the femoral and the iliac artery and we know exactly when it's time to stop.

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NEIL STRICKMAN, MD, FACP, FACC: And, certainly, you can come back with a smaller diameter balloon under high pressure and iron that out if you needed to.

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ZVONIMIR KRAJCER, MD, FACC: That is correct. Hopefully, we will not have to do that. So now we are pulling this balloon out and we'll cannulate the contralateral gate to introduce the left iliac limb.

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NEIL STRICKMAN, MD, FACP, FACC: Now for those of you in the audience, there are slides that will be seen up in the upper corner that we'll be rotating through here. And if there are any questions on those slides, great. As Dr. Krajcer attempts to cannulate the contralateral limb, we'll go with our first question from Kathleen. By Kathleen Almada. And the question

is, I was wondering what are the main causes for a Triple A and do you still do surgery here? Those are really actually good questions. I'll take the say...the second one first. Yes, surgery for Triple A is still done. There are not...not every person is a candidate for endovascular repair. It depends, really, on if there is a so called neck, like a goose's neck that you have to deploy the graft. There are more than one graft available in the United States at the present time. All have some pros and cons to them, so it's an important that you have a so called, a good landing zone. If the patient's aneurysm starts right at the kidney level, or the neck of the aneurysm is too wide for present day devices, then those patients are not good candidates and they do get surgery. And we are actually very involved with our surgeons here. They send us many cases and a visa versa we send them them. So I think it's a really a good rapport.

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ZVONIMIR KRAJCER, MD, FACC: So, I don't know if you have seen or paid attention while Dr. Strickman was talking. There is a quite severe angulation in...to this neck, at the infrarenal neck, and narrowing as well. So, actually, the main...the main body of the limb was obstructing actually the passage of the catheter. And we used a renal double curve catheter; the same one that we used to cannulate the right renal artery to actually give us that angulation that was needed to achieve the access to the contralateral limb. And so we're able to advance this hydrophilically coated wire, which we always use because it...this wire is very torque-able and offers us a lot of support as well because it's super stiff. And now we are advancing the renal double curve catheter. And then through renal double curve we are advancing [Amplade?] super stiff wire. So, at this point we will reintroduce the dilator, 12 French dilator, to negotiate this tortuosity and to advance the 12 French sheath into the bifurcated component of the stent graft. And then we'll deploy the left, or contralateral, limb of the stent graft. So let's see under fluoro. And as you see, there is quite a bit of tortuosity. A significant degree of tortuosity was actually resolved with this super stiff wire. And...and as you can see, now we are...we are in the gate of the...the main body of the stent graft. Now, you might ask yourself, well, how do we know that we are actually through the gate of the contralateral limb and not actually in or behind this...the stent graft or the aneurysm. Well, we know from experience and there are some little tricks that you could use, such as advancing a pigtail catheter and then rotate it in the stent graft. And you can do an angiogram and test. If you are in the stent graft you will see free flow through both limbs and a rapid runoff. But if you are not in it, then you will see a blush or stain of the...the abdominal aortic aneurysm. So, from our experience we are quite convinced that we are in a proper location. Now we are advancing 14.5 millimeter in diameter contralateral limb through the stent graft...or, through the sheath into the stent graft, as you can see here. And it's twelve centimeters in length. And now we'll pull the 12 French sheath all the way below the origin of the stent graft. We can see it well. Now for the sake of completeness and to make sure that we are not covering the left internal iliac, we could do a little angiogram. This is for didactic purposes. I'm quite convinced that we are way above, because we have a reference angio here that we can compare this information with. So let's do a little picture here. Okay. Now you can see on the bottom of the screen the origin of the left internal iliac artery on the replay. And you can appreciate that we are about two centimeters above the origin of the internal iliac. So we are really ready to deploy the stent graft. Let's see the upper part, if you don't mind. That's it. We can maybe move just minimum up. Okay. that's good. And deploy. And you see it opens up real quick. Now there is some narrowing, as you can appreciate there, at the origin of the left common iliac. And we will use a fourteen millimeter in diameter and four centimeter in length balloon to basically dilate this component and to make sure that there is no endoleak or flow around the two components of the stent graft.

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NEIL STRICKMAN, MD, FACP, FACC: Actually, our next question that comes from Terry wondering about endoleak and what are the causes of endoleak, and how do you treat

them, and etcetera? Suffice it to say that there is more than one type of endoleak. The most common is where blood flows back into the aneurysm from a branch of the internal iliac, or so called hypogastric arteries that Dr. Krajcer was pointing out. Sometimes these branches come back and send flow into the aneurysm through the lumbar arteries. That is the most common. It's seen in about ten percent of our cases. But only ten percent of those, or only one percent of the total, actually need to have a subsequent procedure to repair the endoleak. The other endoleaks which may come from the top of the graft if not sealed well, or the bottom of the graft, are noted either at the end of the procedure or on follow-up CAT Scan. And those are treated by either placing another device or some sort of procedure to get rid of the leaking vessels.

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ZVONIMIR KRAJCER, MD, FACC: Okay, very good. Now, as you can appreciate, we inflated fourteen by four balloon at the gate, or overlap between the main body of the stent graft and the left iliac limb. However, there is still a significant narrowing in the left iliac limb and part of the reason is that there is not enough room there, because the infrarenal abdominal aortic is significantly narrowed and it cannot accommodate two fourteen millimeter iliac limbs. So we're going to simultaneously inflate the coated balloon that we have previously used on the right side and a fourteen by four balloon on the left side. And we'll go up now together. Eduardo. Okay. And Ed. And we'll look at the pressures. And we see the pressures. So Eduardo, you can keep it relatively low on the right side. And, Ed, you can go a little bit higher there. Higher pressure, if you don't mind. A little bit higher. Okay. Alright, that's it. Now it has yielded as you can see, and it looks significantly better. So, Ed, you can come down a little bit on your pressure and, Eduardo, you can go a little bit higher there with your compliant balloon. Alright.

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NEIL STRICKMAN, MD, FACP, FACC: So Dr. Krajcer, one of the advantages here is you are able to monitor the patient's pressure because you have each sheath attached to a transducer so you can tell exactly how high pressure you want to go on each balloon. Is that correct?

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ZVONIMIR KRAJCER, MD, FACC: Excellent. Actually, I personally believe that it's mandatory to record pressures. Now, unfortunately, a lot of our surgical colleagues do not do that on a routine basis and, really, you don't know what is going on unless you use pressure monitoring. And I think it's very, very important. Of course, in cardiology we do that on a routine basis, so that...I think it's of great benefit.

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NEIL STRICKMAN, MD, FACP, FACC: Now our next question comes from North Massapequa, New York. And the question is, what keeps the device or the graft from moving? Well, each company has a different fix for that. This particular graft has so called endohooks, or hooks at the top of the graft that when Dr. Krajcer ballooned them in with the coated balloon he's able to make sure that the graft is sealed there. Other devices have either fixation at the same point, or even above the renal arteries, so that when expanded those will keep the graft from moving.

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ZVONIMIR KRAJCER, MD, FACC: So we have completed the procedure now, as far as deployment of the stent graft is concerned, and we'll introduce a calibrated pigtail catheter. And, you can do it through the right side here. Okay, by the right. And we'll take a look.

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NEIL STRICKMAN, MD, FACP, FACC: Our next question then is how is this different from the triple balloon that was seen on another ORLive? Actually, that was probably a thoracic stent graft where the balloon has three lobes to it and at various different sizes and pressure. That is a quite large balloon, up to forty millimeters in diameter. These balloons are much smaller and there is no need for the triple balloon in this procedure.

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ZVONIMIR KRAJCER, MD, FACC: That is correct. So now we'll connect to our power injector and we'll take a look through the angiogram. Hopefully we'll have good results.

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NEIL STRICKMAN, MD, FACP, FACC: Our next question then is, how long does this graft last? And the answer, of course, is forever.

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ZVONIMIR KRAJCER, MD, FACC: Right. Actually, this graft has excellent track record and we've been very pleased. We've been using it for five years and it's a low profile, very flexible, extremely low incidence of thrombosis of the limbs and no incidence of migration in our experience, which is an important aspect. And....

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NEIL STRICKMAN, MD, FACP, FACC: So you are going to make a power injection....

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ZVONIMIR KRAJCER, MD, FACC: That is correct.

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NEIL STRICKMAN, MD, FACP, FACC: ...so that you can see if there is a leak at the top or the bottom, or if the graft is well sealed in all those locations.

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ZVONIMIR KRAJCER, MD, FACC: That is correct.

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NEIL STRICKMAN, MD, FACP, FACC: Now this is pretty unique, Dr. Krajcer, in that you are doing this procedure totally under local anesthesia. There's no general anesthesia. We don't... There is no anesthesiologist in the room. And you're also doing this percutaneous without any surgical access. Is that something that is commonly done throughout the world?

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ZVONIMIR KRAJCER, MD, FACC: Well, I was actually going to mention at the end of the procedure some of our data and experiences with it, and discuss it a little bit further because I think it's an extremely important issue. Of course, we have been doing this for the last ten years at our institution and somewhere around 950 patients had this stent graft procedure done under local anesthesia and percutaneous approach. Unfortunately, this is not done frequently at other institutions and it's estimated at only about two percent of the procedures worldwide are done in this way or under local anesthesia and by a percutaneous approach. Are we ready to do the angiogram? Let's go ahead. Tell the patient to hold her breath.

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SURGICAL NURSE: Take a big breath in. Let it all the way out. Let it out, let it out, let it out. Now hold that breath right there. Don't breathe and don't move. Don't breathe and don't move. Don't breathe and don't move. Don't breathe and don't move. Don't breathe and don't move.

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ZVONIMIR KRAJCER, MD, FACC: Alright. Excellent. Very good.

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SURGICAL NURSE: You can go ahead and relax.

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ZVONIMIR KRAJCER, MD, FACC: a

I think it looks very good. We deployed it exactly where we wanted it, just below the origin of the right renal artery. And, there is a little bit of flow around the stent graft, if you can appreciate that, and so there is always a question is it a Type II Endoleak or is it because the components of the main body of the stent graft and the contralateral limb are not adequately expanded, or is it a Type II Endoleak, or what we call a branch flow endoleak. As you can see, there is a little ulceration there very proximally next to the stent graft.

So...yeah, that did not seal completely in that particular area. So, we're going to re-balloon this one more time, after we put a wire back in, [Amplade?] super stiff wire. And....

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NEIL STRICKMAN, MD, FACP, FACC: Next question then as you're doing that and changing is, how long do the patients stay in the hospital? Ninety-five percent of our patients that get into vascular Triple A stay one night. That is the one night of the procedure. Since this is done totally percutaneously sometimes the next day, if the patients either feel sick or have pain in the groin, they might stay one more day. But almost everyone wants to get up and go home right after they have breakfast, so it's pretty common to stay just one night for the percutaneous endovascular procedure.

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ZVONIMIR KRAJCER, MD, FACC: Um hmm. So, we're gong to use a different balloon that is not as compliant as this particular coated balloon is that we used originally. It's an impact balloon, or a Z-med, produced by Braun. It's a noncompliant balloon that, hopefully, will seal this endoleak, or flow, around the stent graft.

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NEIL STRICKMAN, MD, FACP, FACC: Now, Dr. Krajcer, do you think this come...is coming from the top of the graft and that maybe if you had the high pressure noncompliant balloon this will seal that in, or do you think this is coming from lumbar collaterals?

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ZVONIMIR KRAJCER, MD, FACC: I think it's coming from above. I think...or, due to irregularities in the neck. This is an ulcerated and kind of diseased aorta, but I would like to have your opinion as well, Neil.

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NEIL STRICKMAN, MD, FACP, FACC: Yeah, to me it looks like it's coming from the top. You can see flow into the aneurysm. You have that large bulbous ulcerative area.

ZVONIMIR KRAJCER, MD, FACC: Right.

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NEIL STRICKMAN, MD, FACP, FACC: And I think the right thing to do is to hit it harder with a noncompliant balloon as you're planning to do here.

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ZVONIMIR KRAJCER, MD, FACC: Of course, another option would be if this is truly a Type I Endoleak from above, to extend this stent graft and put a what we call aortic cuff. We, I think, have about two millimeters available below the origin of the right renal artery.

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NEIL STRICKMAN, MD, FACP, FACC: That certainly can be done if after this balloon intervention---

ZVONIMIR KRAJCER, MD, FACC: Right.

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NEIL STRICKMAN, MD, FACP, FACC: ---the results are not satisfactory. And the reason that can be done is this graft has like a sign wave appearance at the top that it scallops. And so they're...even though you're seeing those three markers that Dr. Krajcer just showed you, there is some areas that where the stent graft actually has like peaks and valleys, so it's not totally covered to the top where you see those black markers. Our next...next question comes from Alex and his question was, since the right renal artery is so...was so much lower, do you see cases where one renal artery is so low that it gets in the way of doing the endograft? And that is a definite yes. There are cases that we either have the right renal artery reimplanted or we don't do the case and have the surgeons reimplant it during the surgical repair. Because, if there are...if the right or left renal artery takes care of the whole kidney, then you don't want to sacrifice that. Now there you see Dr. Krajcer has inflated the...the high pressure noncompliant balloon. And they now are deploying that back, doing it twice again. The hooks are right underneath of those black markers that you are seeing up top. Now since we know there's no endoleak at the bottom, the next picture

that's taken with the pigtail catheter can really concentrate and see if there's contrast that flows into the aneurysm. It's interesting, Dr. Krajcer, that as you look at this picture you can see that there is contrast that has lined the walls of the calcium of the aneurysm, which was present before. So for the audience, they can see exactly how large that aneurysm really is.

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ZVONIMIR KRAJCER, MD, FACC: Okay. Let's put a pigtail on the left side. We'll repeat the angio now. Right. And, Neil, you don't think that there is any flow between the iliac deployment....

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NEIL STRICKMAN, MD, FACP, FACC: Doesn't look like it to me.

ZVONIMIR KRAJCER, MD, FACC: Okay. Alright.

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NEIL STRICKMAN, MD, FACP, FACC: It looks like it's all coming from the top.

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ZVONIMIR KRAJCER, MD, FACC: Uh huh. Uh huh. Alrighty. Um hmm. Okay, we'll---

00:36:22

NEIL STRICKMAN, MD, FACP, FACC: So as you're placing that catheter up, our next question comes to us from Seattle and it's, what's the risk of recurrence after the endovascular repair? Well, I would say that there's a ten percent risk of endoleak and a one percent risk of the endoleak needing something done. There are some cases though that despite doing an excellent job and we see no evidence of endoleak, and on CAT Scan we don't see any contrast in the aneurysm, the aneurysm continues to grow, a so called Type V Endoleak or Endotension. So, it's a very small percentage, but it does occur. That is why we stress for all of our patients when we do this that they need to have follow-up of a CT Scan at one year. Unfortunately, the...now many patients don't return for that, or maybe have them done where the x-ray equipment is not as good as we desire and the 3D imaging is not as well. But, certainly, patients who have continued to be monitored with CT Scans at a yearly basis, if they have any problem, they're picked up, we can repair these without surgical conversion. And Dr. Krajcer will go over some of the Texas Heart Institute results at the end of the case and show you. And then, certainly, if you have other questions about that we can show that to you.

00:37:40

ZVONIMIR KRAJCER, MD, FACC: Okay. So we're going to give a twenty cc's here. Alrighty.

00:37:46

NEIL STRICKMAN, MD, FACP, FACC: And we'll be concentrating at the top, where you see the pigtail catheter.

00:37:51

ZVONIMIR KRAJCER, MD, FACC: Right. Okay, are we ready to tell the patient to hold her breath? Alright.

00:38:13

SURGICAL NURSE: You need to take a big breath in. And let it out. All the way, all the way. Now hold your breath right there. Don't breathe and don't move. Don't breathe and don't move. Don't breathe and don't move. Don't breathe and don't move.

00:38:28

ZVONIMIR KRAJCER, MD, FACC: Good. Excellent. Alrighty, so---

SURGICAL NURSE: You can breathe normal.

00:38:33

ZVONIMIR KRAJCER, MD, FACC: This looks very good. But, there is still a little bit of flow there. So we have to make sure that it's not the...that the gate, because it looks like it could be coming at the gate there. So I would suggest to try to dilate this gate one more time. Okay?

00:38:54

NEIL STRICKMAN, MD, FACP, FACC: You could also inject contrast directly into that gate, if you desire. If you have the chance.

00:38:58

ZVONIMIR KRAJCER, MD, FACC: Which...which we will right now. So this is...this is what we're going to do right now with hand injection. And just verify this. Otherwise, we have an option to use a cuff, aortic cuff, and extend this device higher up. So, are we ready? And we're going to put it on one mag so we can see better. Right. We could angulate it. Alright, so let's do this, okay? So this is going to be a hand injection. Alright. Can we tell the patient to hold her breath?

00:39:40

SURGICAL NURSE: Take a breath in. Let it out. Let it out. Now hold it. Don't breathe. Don't breathe. Don't breathe. Don't breathe.

00:39:51

ZVONIMIR KRAJCER, MD, FACC: Okay. So we have documented that actually it's not coming around the gate or overlapping components. So, we are strongly suspecting that it's either coming from above and, therefore, we're going to place an extension cuff just above the current stent graft.

00:40:18

NEIL STRICKMAN, MD, FACP, FACC: Great. As we mentioned before, the graft has like a sign wave of peaks and valleys to the top of it, so it's not totally covered in a straight line. So if you put an extension cuff of a larger diameter in that area, that should be able to cover the peaks and valleys that are there and cover the line of the lower right renal artery. Now, the size of the extension cuff, what, will be twenty-six or twenty-eight port hole?

00:40:41

ZVONIMIR KRAJCER, MD, FACC: Twenty...Twenty-six, right.

00:40:43

NEIL STRICKMAN, MD, FACP, FACC: A twenty-six millimeter cuff and that is 3.3 centimeters in length...

ZVONIMIR KRAJCER, MD, FACC: Right.

00:40:48

NEIL STRICKMAN, MD, FACP, FACC: ...so you are not in danger of this crossing one or other of the limbs. This should sit perfectly inside the main body of the ipsilateral trunk, because that is four centimeters from the top of the graft to the split that's closing to the left and right leg. And here you watch Dr. Krajcer placing this very short aortic extension cuff through the eighteen French sheath and that he will plant it above.

00:41:17

ZVONIMIR KRAJCER, MD, FACC: So we're advancing the aortic cuff through the stent graft, as you can see it here.

00:41:26

NEIL STRICKMAN, MD, FACP, FACC: Now you may want to get more angulation or less angulation, depending---

00:41:28

ZVONIMIR KRAJCER, MD, FACC: Right. Absolutely.

00:41:29

NEIL STRICKMAN, MD, FACP, FACC: ----on what is needed at that point.

00:41:31

ZVONIMIR KRAJCER, MD, FACC: Where we'll magnify it now. We'll take another picture. And, so we'll know exactly where we are. We are about nineteen degrees angulated. Now we are about twenty-three. So we'll ask the patient, again, to hold her breath.

00:41:50

SURGICAL NURSE: Take a breath in. Let it out. Hold it right there. Hold your breath. Hold your breath. Hold your breath. Hold your breath.

00:42:00

ZVONIMIR KRAJCER, MD, FACC: Okay. Very good. Now we can mark the origin of that right renal artery. Okay. So...

00:42:13

NEIL STRICKMAN, MD, FACP, FACC: So, Dr. Krajcer, it still looks like you have maybe three millimeters, or so, above the stent graft and below the right renal artery to implant this extension cuff.

00:42:24

ZVONIMIR KRAJCER, MD, FACC: Right. Do you think that this is the right position, or...

00:42:29

NEIL STRICKMAN, MD, FACP, FACC: Well, I'll have to see it one more time.

00:42:30

ZVONIMIR KRAJCER, MD, FACC: Pull it down a little bit lower. Uh huh.

00:42:34

NEIL STRICKMAN, MD, FACP, FACC: I wonder if...I wonder if angulating it just a smidge differently would have been helpful.

ZVONIMIR KRAJCER, MD, FACC: Right.

00:42:42

NEIL STRICKMAN, MD, FACP, FACC: I don't know, this looks like it's above it, so.

00:42:44

ZVONIMIR KRAJCER, MD, FACC: Well, it...What we can do is pull the wire back. Maybe it will accommodate and follow...the contour really doesn't...doesn't do that, so...Another way to do it is pull the wire back and bend it, which we have done in the past. And let's see if that does it. Okay.

00:43:05

NEIL STRICKMAN, MD, FACP, FACC: So if you bend the stiff portion of the wire you can actually make that graft turn left or right, correct?

00:43:12

ZVONIMIR KRAJCER, MD, FACC: We hope so.

00:43:14

NEIL STRICKMAN, MD, FACP, FACC: We do too.

00:43:17

ZVONIMIR KRAJCER, MD, FACC: Okay. Let's see now with using this bend on the wire if we can do that. Okay.

00:43:27

NEIL STRICKMAN, MD, FACP, FACC: A little...Look at that. Wow.

00:43:28

ZVONIMIR KRAJCER, MD, FACC: You like that?

00:43:29

NEIL STRICKMAN, MD, FACP, FACC: I hope the audience saw that. That was great.

00:43:31

ZVONIMIR KRAJCER, MD, FACC: Do you think we should be a little bit higher? Just a little bit. Right like this. Alright.

00:43:36

NEIL STRICKMAN, MD, FACP, FACC: Do you have the marker on your screen? Are you comfortable with that?

00:43:38

ZVONIMIR KRAJCER, MD, FACC: Yes. We do have a marker on the screen here. You don't think we should be going a little bit higher? No.

00:43:42

NEIL STRICKMAN, MD, FACP, FACC: I want to know what the blood pressure is.

00:43:44

ZVONIMIR KRAJCER, MD, FACC: No, it doesn't matter, honestly, in this particular scenario. Alright. That looks good. Well, anyhow.

00:43:54

NEIL STRICKMAN, MD, FACP, FACC: So this is nice. The pigtail is there. You can accurately push it up and know within seconds whether you have found the endoleak or not.

00:44:02

ZVONIMIR KRAJCER, MD, FACC: Right. Exactly. Now we're going to use that impact balloon to...Right. To try to expand that stent graft. You can push the wire up higher. That's it. Excellent. So, actually, this case appears to be a little bit more complex and interesting than we originally thought, because with four centimeter neck you would think that you have to...that you would have adequate seal. But, this patient has a lot of ulcerations and irregularities, and this is what's causing a problem.

00:44:43

NEIL STRICKMAN, MD, FACP, FACC: And sometimes the stent grafts don't deploy in a straight line....

ZVONIMIR KRAJCER, MD, FACC: Right.

00:44:47

NEIL STRICKMAN, MD, FACP, FACC: ...or vertical line.

00:44:50

ZVONIMIR KRAJCER, MD, FACC: So, we...for the sake of making sure that we are not covering the renal, we could test a little bit here on the pigtail side.

00:45:00

NEIL STRICKMAN, MD, FACP, FACC: I would do that, just----

00:45:01

ZVONIMIR KRAJCER, MD, FACC: Yeah, it looks perfect, actually. It looks very good.

00:45:03

NEIL STRICKMAN, MD, FACP, FACC: Show it one more time. We missed that. Could you show that one more time?

00:45:06

ZVONIMIR KRAJCER, MD, FACC: Yeah, we can take a picture, actually. Let's take a picture.

00:45:09

NEIL STRICKMAN, MD, FACP, FACC: After you take a good enough picture, you'll know if there's an endoleak.

00:45:13

ZVONIMIR KRAJCER, MD, FACC: Right. Okay, we'll...Hold your breath right now. Hold your breath. Excellent. Excellent. I'm sorry. Okay.

00:45:22

NEIL STRICKMAN, MD, FACP, FACC: And no endoleak.

00:45:22

ZVONIMIR KRAJCER, MD, FACC: Right.

00:45:24

NEIL STRICKMAN, MD, FACP, FACC: Two for one.

00:45:26

ZVONIMIR KRAJCER, MD, FACC: Right. Right, please do. Please, do.

00:45:29

NEIL STRICKMAN, MD, FACP, FACC: Dr. Krajcer, this is a great question for you. This comes from Agatha and she says, is the stent graft the same as the kissing stent. Well, I know that you and I have both been Latin lovers in our life, but this is not really a kissing stent, is this?

00:45:45

ZVONIMIR KRAJCER, MD, FACC: No. No, not at all. Not at all.

00:45:48

NEIL STRICKMAN, MD, FACP, FACC: Right. And she also asks, what drugs will be used? Actually, the patient gets intravenous Heparin as a blood thinner throughout the case. Maybe a little sedation with whatever medicine you desire. And that's it. The Heparin is

reversed at the end of the procedure. The areas of access are tied off percutaneously with the so called preclose procedure. And no other medicines are needed. They get antibiotics before and after the procedure, just as any surgical procedure is done.

00:46:17

ZVONIMIR KRAJCER, MD, FACC: Right. Okay. So, we can take another little picture here. Shortly. We need a little bit of pressure on this right side. Please. Okay. So...eleven. And, Dr. Hernandez, he's a very powerful gentleman. He'll take a little picture right here. A little hand injection. Okay. Are we ready? Okay. Can we tell the patient to hold her breath? That is fine. Perfect there. Yes? Please.

00:47:06

SURGICAL NURSE: Take a breath in. Let is out. Let it out. Now hold it right there. Don't breathe. Don't breathe. Don't breathe.

00:47:16

ZVONIMIR KRAJCER, MD, FACC: Alright, this looks excellent. I think we have resolved this problem.

00:47:21

SURGICAL NURSE: Breath normal.

00:47:22

NEIL STRICKMAN, MD, FACP, FACC: And the cuff saves the day. Very good.

00:47:24

ZVONIMIR KRAJCER, MD, FACC: Right. Excellent. Excellent.

00:47:26

NEIL STRICKMAN, MD, FACP, FACC: And I think it's because of the scallops of the graphic, because it's not the...totally straight across the top. This is really a great thing to have. You have to become very familiar with this if you're doing endografts.

00:47:39

ZVONIMIR KRAJCER, MD, FACC: Alright, so what we are gong to do now is we'll put a catheter here on the right side and then the super stiff guide wire, if you don't mind. And, I will show you the technique of making a sliding knot, or a fisherman knot, or a clench knot, to actually close this femoral artery access site. And, we'll use some flush here as well. And, let's get all the equipment here that I need. Well, I was not talking to you, but we are doing fine. We are doing just great. Are you doing alright? Okay. Great. Great. So, here we have a green suture, as you can see. And so we'll use a sliding knot and we'll go five times around. This is twice, three, four, five. Okay. Now we'll go through the loop and come out here. And this is what we call a fisherman knot or a sliding knot. So this is for the green suture. And here we have the white suture, or the Prostar XL, as you can see. One, two, three, four, five. We can give local on the other side. And we go through the loop and around your rail, and here you have a knot, fisherman knot.

00:49:30

Go ahead. Okay, now we'll give a little bit of Zilocaine for a local anesthesia. Okay, we can advance this all the way up holding the wire. And we'll put a...

00:49:44

NEIL STRICKMAN, MD, FACP, FACC: Again, if there are any other questions, you have your final ten minutes. We would be willing to take any of those at the present.

00:49:52

ZVONIMIR KRAJCER, MD, FACC: Um hmm. So this is local anesthesia just to numb the area a little bit more, so it doesn't hurt during the procedure. And here. A little bit more. Alright. So that's it.

00:50:26

NEIL STRICKMAN, MD, FACP, FACC: So you've just given local Zilocaine for comfort of the area where you punctured?

00:50:32

ZVONIMIR KRAJCER, MD, FACC: That is correct.

00:50:33

NEIL STRICKMAN, MD, FACP, FACC: And you have tied two separate sutures in the fisherman's knot.

00:50:37

ZVONIMIR KRAJCER, MD, FACC: We need a dilator.

00:50:38

NEIL STRICKMAN, MD, FACP, FACC: So that when the catheter is pulled out it will make that "x" across the opening and close the hole.

00:50:44

ZVONIMIR KRAJCER, MD, FACC: That is correct. So now we'll introduce the dilator and this eighteen French sheath. We have Dr. Livesay here next to us; an excellent cardiovascular surgeon and vascular surgeon. He can help us in case we have any difficulties in achieving a complete success with closure of this femoral artery. And Dr. Hernandez, who now is performing what we call a sliding knot technique here repairing the left femoral artery. So he'll go five times around and then he'll go through the loop. Excellent. We'll need some flush there. This is antibiotic solution. So one is done here and we need one more.

00:51:57

We need a little bit longer rail because she's a skinny lady. Okay, keep going. One, two, three, four, five. Okay. I'll go through that loop and I can also hold it for you, if you want. And that makes it easier.

EDUARDO HERNANDEZ, MD: Thank you.

00:52:18

ZVONIMIR KRAJCER, MD, FACC: Alright. Mucho gusto. Okay. We can flush it again. Excellent. Excellent. So, now comes the moment of the truth. We'll pull this right sheath out. And, Ed, you're going to slowly pull this for me. Hold on just one second. Okay. Ready. Okay. Slowly. Slower than that. Okay. Slower. Alright. Excellent. Excellent. Flush it a little bit. Stop. Flush it. Excellent. That's good. Alright. Alright, pull now. Pull now. Alright, excellent. Hold on just one second. Excellent.

00:53:25

NEIL STRICKMAN, MD, FACP, FACC: So there is the removal of a large bore sheath, eighteen French.

00:53:28

ZVONIMIR KRAJCER, MD, FACC: Okay, now hold your wire.

00:53:30

NEIL STRICKMAN, MD, FACP, FACC: And the...the hole seems to very adequately closed.

00:53:35

ZVONIMIR KRAJCER, MD, FACC: Right. So here you have excellent hemostasis and the patient that is fully anticoagulated. As a matter of fact, her ACT was 300 seconds, so she is fully anticoagulated. Normally we don't reverse Heparin unless we have to. And this is an knot pusher that also comes with the device. And, that helps driving the knot further down to the origin of the artery. So, we do it on the white suture and then we do it on the green suture. Right here. And when we are satisfied with adequate hemostasis then we can lock this knot by pulling on the non-rail, here you can see. On the non-rail. And we do the same thing on the green suture, here you can see it, and pull on the non-rail. So, we can leave this for now like this until we are done with the other side to kind of temper...temporarily our access site. And, then we can work on the other side.

00:54:53

And the ideal approach is always to put a wire through the catheter that's hydrophylically coated. Braided wires are not good. The reason for it is that the suture will clamp onto the braided component of the wire and it will strip it while we're trying to pull it, if you advance the knot far down. So, here we have the hydrophylic wire in place. And....

00:55:27

NEIL STRICKMAN, MD, FACP, FACC: What's the largest size sheath that can be closed with this percutaneous approach.

00:55:31

ZVONIMIR KRAJCER, MD, FACC: Yeah, that's very appropriate question. Twenty-four. We have done it for thoracic aneurysm repair and twenty-four sheath, so...Alrighty.

00:55:46

NEIL STRICKMAN, MD, FACP, FACC: So, again, Dr. Krajcer, this whole case was done under local medicine, percutaneous with Zilocaine anesthesia, correct?

00:55:52

ZVONIMIR KRAJCER, MD, FACC: Right. Right. That is correct. Go ahead. Go ahead. Go ahead. Keep going. Okay. Excellent. Pull the wire. It has to be a gentle pull, as you can see here. It shouldn't be overly aggressive. And...we need a knot pusher now. Thank you.

00:56:24

NEIL STRICKMAN, MD, FACP, FACC: That's great. Well, it's really been very exciting to be able to watch you do that.

00:56:28

ZVONIMIR KRAJCER, MD, FACC: So, basically, we're going to put a little...little sterile strip on it and we'll be done here. Eduardo, maybe you can finish this, just tightening the knots and locking that. And, in the meantime, I would like to show you a few remaining slides, if we have about four or five minutes left, to look at our results and indications for this procedure. So, again, you can see the sliding knot technique that we have shown you previously. Next. And then pulling on the rails advancing the knot through the arteriotomy. Next one please. Here pulling the sheath further out. Next one. And then basically the only thing that remains is the wire in the artery. And if we have excellent hemostasis, then in that...that point of time – next – we can use a knot pusher to tighten the knot. And you can see a schematic drawing on the right hand side, the way this knot will seal the of the...the actual site of the femora...or, femoral artery. Next please. And this is how it will look at the end. A little tiny incision and one sterile strip will achieve a good result and heal the area at the access site. Next one please. Now, as I have mentioned previously, unfortunately only a small percentage of patients under regional anesthesia or spinal anesthesia, which is a less aggressive approach than general anesthesia for femoral artery repair during endoluminal treatment of abdominal aortic aneurysm. Eighty-two percent still receive general anesthesia, which is very aggressive approach for treatment of this condition. And from the clinical trials, as you can see...next...we can see...next...that a very small percentage undergo this procedure with the use of local anesthesia and percutaneous approach. When we look at the clinical trials that were carried on in the United States, the incidence of complication with surgical access for stent graft procedure could be up to twenty percent. And up to eleven percent of patients can have a complication such as vascular complications of the procedure. Next one please. So, why percutaneous approach and why local anesthesia? Well, the purpose is to avoid the risk of surgery, the risk of anesthesia and to reduce patient discomfort and reduce the hospital stay, and offer the patient a quicker return to their normal lifestyle, which was clearly shown in the clinical trials that were carried on in the United States and also abroad. Next one please. At our institution since 1995, 1,226 patients underwent abdominal aortic aneurysm repair with various types of stent grafts. And 941 patients had a percutaneous repair with the use of local anesthesia. Next one please. Our technical success rate was a hundred percent. There were no conversions. Peri-procedural mortality was 0.2 percent. And the success of femoral artery repair with large diameter sheaths was ninety-five percent. It was significantly higher for lower profile sheaths such as twelve French. It was ninety-eight percent. And the average return to a normal diet is one hour, which is of great benefit since after surgery it takes up to five days or longer for the patients to be fed with a normal diet. And we usually ambulate our patients eight hours after the procedure. And they're usually discharged twenty-four hours after the procedure. Next one please. So, when we compare

our experiences with local anesthesia and percutaneous approach with the general anesthesia and surgical femoral artery repair we can see that we can...next...reduce the...next...the duration of the procedure, less stay in the holding area of the cath lab, less blood loss and less need for blood transfusion and shorter hospital stay. Next one please. When we look at the complications such as growing infection, femoral neuropathy, hematoma, and so on, again...next...there is a significantly lower incidence of vascular complications with percutaneous approach, than...next...with surgical approach. Next one please.

01:00:41

So, we can say in summary that this approach offers the patient a great benefit, as you have seen in our patient that had multiple co-morbid conditions. And I believe that this will be the approach in future as well. I don't see any reason why not to use this approach if we can offer a patient less complications and better lifestyle at the procedure. And, at the end we can see the exit sites, if we can focus on it. No bleeding. The Heparin has not been reversed. And we'll put sterile strips and we'll...we'll be done. Neil, thank you very, very much for helping us during the procedure and give us...giving us spiritual guidance as well as information related to the procedure, per se. Do you have any comments in addition to what we have mentioned?

01:01:29

NEIL STRICKMAN, MD, FACP, FACC: I'd like to say in closing that this was a great demonstration of how one can take a patient with a life threatening illness such as an infrarenal abdominal aortic aneurysm and have the patient fixed without general anesthesia in a cardiac cath lab in one hour or less with very low risk. I'd like to thank the audience for sending the questions in and for everyone out there, and for watching us from the Texas Heart Institute at St. Luke's Episcopal Hospital, Houston, Texas. Thank you.

01:01:58

ZVONIMIR KRAJCER, MD, FACC: Neil, thank you very much. I would like to thank my colleagues that helped me here – Dr. Livesay and Dr. Hernandez, and Ed Minor. Sam, thank you very much. I appreciate very much your help in this case.

01:02:15

NEIL STRICKMAN, MD, FACP, FACC: Thank you.

01:02:16

ANNOUNCER: This has been an endovascular repair of an abdominal aortic aneurysm with the Gore Excluder AAA Endoprosthesis, performed from St. Luke's Episcopal Hospital and Texas Heart Institute in Houston, Texas. ORLive makes it easy for you to learn more. Just click on the "Request Information" button on your webcast screen and open the door to informed medical care.

01:02:42

[END OF WEBCAST]