GEORGE DANGAS: Welcome from all around the world to structured heart life cases broadcasting from the Cardiac Catheterization Laboratories is of Mount Sinai Hospital in Mount Sinai Heart in New York City. I'm Dr. George Dangas and will be the moderator for today's very exciting case. Let me let you know that the video for this case will be available at the website that you're watching from later today.

The last broadcast from July 10 and all previous structural heart life cases are available at this time at ccclifecases.org, the website that you're watching from. We'd love to hear from you during the case, and if you bring me any questions through email at info@ccclifecases.org, I will bring them over to the discussion during the case. So let's move ahead to the great case we have from the Cardiac Cath Lab today. And let's me Dr. Sharma, Dr. Kini, and the rest of her team.

SAMIN SHARMA: All right. Good morning, George, and good morning to our viewers of special heartlifecases.org. And this is episode number 25th.

And we have provided various kinds of flavor of structural cases. Last time in July was a vital clip. Before that early in March was the TMVR. And today, we had the patient with the for TAVR, particularly patients who already have a mitral valve replacement.

So we are done. And now on this case, this will be the second case which we are done. We had a mitral valve replacement before earlier many years ago. And now we have the TAVR procedure.

With that note, I with my [INAUDIBLE] today's-- our faculty and staff here, Dr. Kini on the left side, Dr. [INAUDIBLE], our surgeon. On the right side, then, Assad Khan, our junior attending or [INAUDIBLE] structural heart attending, soon becoming senior.

And then we have a fellow Nish Patel. And of course, the rest of the cath lab staff-- we have anesthesia, Dr. Benjamin [INAUDIBLE] and on the echo with Dr. [INAUDIBLE]. And actually Dr. [INAUDIBLE] had joined us from Atlanta.

So we'll be-- really, we have a wide range of expertise trying to do any complex case just like for the coronary case. So with that note, we can start with the slide presentation. [INAUDIBLE] next, next.

So this is an 87-year-old female, began as a progressive severe dyspnea, class 3. For a few months, patient had bio-prosthetic MVR and tricuspid valve repair back in May 2014. She does have thrombocytosis and has atrial fibrillation, hypertension, hyperlipidemia, on warfarin and other medicines and basically severe aortic spinosis. Coronaries are normal and normal ejection fraction. Next.

So we actually can go to the life echo. Although we can play, the first button is [INAUDIBLE] will be to play. But we can see severe aortic stenosis.

But we'll ask Dr. [INAUDIBLE] to show the live echo. Can we show the linebacker? Good.

SPEAKER 1: Yep. So we can see that this patient has a mitral bio-prosthetic valve and a tri-cuspid valve repair. She also-- sorry. She also has very [INAUDIBLE] aortic valve with pretty severe aortic insufficiency as well as aortic stenosis. She has moderate tricuspid regurgitation. She also has a high gradient across her mitral prosthesis with [INAUDIBLE] and overall normal ejection fraction, no pericardial infusion to start the procedure.

SAMIN SHARMA: OK. So [INAUDIBLE], in terms of the mitral, mitral it about 40 years old. Looks good, right, on the--

SPEAKER 1: A mean gradient of eight.

SAMIN SHARMA: Mean gradient of eight.

SPEAKER 1: So slightly on the high side but unchanged from before.

SAMIN SHARMA: What do you think about with the mosaic-- the mitral point of view? I mean, this [INAUDIBLE] is 40 years, looking good. Further chance--

SPEAKER 2: This patient had prosthesis implanted at the age of 83. It's a valve which is the smallest mitral valve-- 25 millimeter. But considering her body [INAUDIBLE] area, it's quite a good size without probably any patient prosthesis mismatch. So she should do well with this valve for years to come.

SAMIN SHARMA: OK good. OK, let's continue our presentation. Now [INAUDIBLE], you take over.

SPEAKER 3: Yep. So these are some of the CTA measurements we used for sizing this valve. As you can see, it's a fairly non-hostile aortic valve, and the mean average diameter of the aortic annulus is around 23 [INAUDIBLE] on the upper boarder range of 26.2.

Next slide, please. So [INAUDIBLE] fairly generous. The mean is around 32. STJ height is very favorable. The interesting point here is probably the alveolar diameter, which gets a bit smaller.

And that was one of the reasons we went with the [INAUDIBLE]. And that will play a role in determining the sizes for our pre and post [INAUDIBLE] balloons as well. The semi-aortic diameter is fairly good. Next slide, please.

SAMIN SHARMA: And the coronary heights-- if we can go back, coronary heights are good. Always I emphasize that more than 10 is good, although some people say 12. But more than 12 is good, and you have-- the sinus and Valsalva are more than 30. So that's good in terms of less chances of coronary obstruction.

SPEAKER 3: Especially in case of Evolut valve. And you're good wide sinuses and reasonable heights is very low risk of [INAUDIBLE]. Next slide, please. So these are the femoral exits. [INAUDIBLE]

SAMIN SHARMA: Pretty good.

SPEAKER 3: Which are pretty good, yeah-- very favorable and non-hostile.

SAMIN SHARMA: Yeah.

SPEAKER 3: Next slide, please. So in this case, we-- as with [INAUDIBLE] case, we do have [INAUDIBLE] center for central device. And it's a fairly reasonable [INAUDIBLE] anatomy for central insertion.

Next, please. So based on all these measurements we decided to go with the 26 Evolut-PRO valve. Next, please.

SAMIN SHARMA: Which fits into all the criteria.

SPEAKER 3: Which fits all the criteria.

SAMIN SHARMA: So clearly, heart team, it a high risk. Actually, the initial announcement which we made, although we have changed today, intermediate. But then we put all that notes together. And it's clearly a high risk.

And there was a change in [INAUDIBLE] better measurement of the aortic annulus. So valves felt to be 26 to be appropriate with a central device. And that's where we are. Now what you have done so far, Assad?

SPEAKER 4: So now [INAUDIBLE]

SPEAKER 3: [INAUDIBLE]

SPEAKER 4: [INAUDIBLE]

SPEAKER 3: Yep.

SPEAKER 4: [INAUDIBLE] this is the non-excercise and exercise [INAUDIBLE]

SPEAKER 3: You can see fairly reasonable.

SAMIN SHARMA: Go back on fluoro now.

SPEAKER 3: This-- so before opening our central device, we would do an extreme [INAUDIBLE] projection [INAUDIBLE] which again confirmed that the great vessel anatomy is fairly suitable. This is, again, [INAUDIBLE] angle. We'll discuss it later.

This is a big sheet going up. This is us checking the valve pretty good. We could check the [INAUDIBLE]. So this was putting the--

SPEAKER 4: [INAUDIBLE]

SPEAKER 3: Yeah [INAUDIBLE]

SAMIN SHARMA: OK, [INAUDIBLE] next.

SPEAKER 1: [INAUDIBLE] already?

SPEAKER 3: So this is us deploying the [INAUDIBLE] device, fairly reasonable [INAUDIBLE]

SAMIN SHARMA: So now let's talk about sentinel, knowing that the recent recommendation for the national coverage determination will start reimbursing this device by next month How much exactly, we don't know. Device we know costs around $3,000.

But the timing-wise, there is various reports. Some people say it doesn't add much to the time. Some people say it takes 15 minutes.

What do we think the timing-wise? And who is doing it? Fellow is doing it or attending is doing it?

SPEAKER 3: So fellow starts with being the second [INAUDIBLE].

GEORGE DANGAS: We hear some echo in the back, and that's-- we can't hear the second conversation. So please concentrate to Assad and Dr. Sharma. The other persons are not heard.

SAMIN SHARMA: Yeah.

SPEAKER 3: Yeah, so it's a device that [INAUDIBLE] you need some practice with it. And I think about after doing-- a fellow, after doing four to five devices under supervision, we can start deploying. It's just like any other interventional procedure. It needs some hands-on experience. But it's something that you can pretty easily matter if you start getting [INAUDIBLE] even then go towards complex ones.

SAMIN SHARMA: But how much time will it take? Adds to your TAVR--

SPEAKER 3: So today, it took us less than two minutes, we would run out of time anyway. And then it was pretty quick. Again, this anatomy is very reasonable and very easy to maneuver around. For difficult ones, it can take up to 5 to 10 minutes.

SAMIN SHARMA: I mean, that's really a good point. I see-- I mean, it's a very funny design but great engineering setup that how this U-shaped umbrella gets into both of them. And I've seen our attendings here do it within two to three minutes so that, yes, at a negative point would be maybe, let's say, total five minutes extra floor time and one shot of the angiogram.

SPEAKER 3: Yeah, [INAUDIBLE].

SAMIN SHARMA: [INAUDIBLE] which in some cases you need. Other one, if there is an issue about the kidney, you can always deliver your landmark [INAUDIBLE] received on the CAT scan.

SPEAKER 3: Agreed

SAMIN SHARMA: [INAUDIBLE] you want to make a comment on this filter device?

SPEAKER 1: No. Unless you have a perspective data at that time, OK? Everything is two minutes. So I think you have to-- which I have told you guys that you start, press zero as soon as you start the procedure, and then collect that time.

SPEAKER 3: Actually, in this case, you [INAUDIBLE] the whole thing, putting device in, which is pretty quick.

SPEAKER 1: The biggest problem is I know that different people have different numbers. I think the real world experience, the issue always is the radial anatomy.

SPEAKER 3: Yeah.

GEORGE DANGAS: Yeah, can we--

SPEAKER 1: Access radial anatomy, [INAUDIBLE].

GEORGE DANGAS: Once we talk about sentinel, let's just-- Assad, just go-- just say the steps on the beginning. Just say Dr. [INAUDIBLE] brings up a very important thing, that--

SPEAKER 3: So I don't know if we can show the-- yeah, we have [INAUDIBLE] the device insertion thing.

SAMIN SHARMA: You're the next one. [INAUDIBLE]

SPEAKER 3: Yeah.

SAMIN SHARMA: Yeah.

GEORGE DANGAS: Just say all the steps from the time--

SPEAKER 3: [INAUDIBLE] the way we do it is after confirmation of anatomy on the CTA, we will do an extreme [INAUDIBLE] picture. We will fix that picture as a reference image while we are deploying it. We will go in with that. So how--

SAMIN SHARMA: Radial puncture.

SPEAKER 3: Radial puncture. After that, once everything is suitable, then we'll do the radial puncture. Following that, we put a [INAUDIBLE] GR4.

And inside that, [INAUDIBLE] either depending on how tortuous the vessels are, we'll use either the feeler wire or the grand slam wire. Here, we use the feeler wire to navigate the anatomy. So once we-- and before we open the device, we will try to wire both the carotids with the feeler wire by the GR4 catheter.

Once we're able to do all that, then we open the device. Following that, the device is inserted all the way down into the ascending aorta. At that point, you deploy the first filter. And following that, you will withdraw the wire a bit into the device curve the device up.

What we have found is it's faster to wire the left carotid from a bit lower down because it gives you more area maneuvering. Once you wired it with your feeler wire, then you pull back, hook the carotids, and deploy the second filter. And then you lock it.

SAMIN SHARMA: And that is how you did.

SPEAKER 3: Yeah, it's all [INAUDIBLE].

SAMIN SHARMA: Yeah. OK, so once it is in position-- and then always the issue comes when you are advancing your device across the optic arch that can you take the filter down. But actually, in the trial, the real life has not been really reported. But I'm sure it will be under reported. But I will say that we haven't had any trouble and nor also in the trial that as long as you are careful, you are flexing your TAVR catheter, whether it's the [INAUDIBLE] or core valve, that you are able to navigate through the even complex arch anatomy after the full good deployment of the central device.

SPEAKER 3: Yes. One of the things we have done is that we keep our [INAUDIBLE] and AR2 [INAUDIBLE] one catheter the great vessels while we are deploying it so they don't get hooked into the device just to avoid the wire getting entangled.

SAMIN SHARMA: OK, with that note, we are ready to start of any particular angle you have.

SPEAKER 3: Yeah [INAUDIBLE].

SPEAKER 1: So you're telling me all this is done in two minutes?

SPEAKER 3: Yeah. We have [INAUDIBLE] save time. This one is--

SAMIN SHARMA: Oh, but it does take-- but it doesn't take too much time.

SPEAKER 1: I'm telling you. Getting radial access to placing the sentinel, you're adding extra 25 minutes.

SPEAKER 3: Actually, we got the [INAUDIBLE] while we were doing echo images. So it didn't [INAUDIBLE]

SAMIN SHARMA: Can I make a comment [INAUDIBLE] four years ago [INAUDIBLE]? So other question is actually, I had that question why we should put a [INAUDIBLE] are crossing the valve. The question was, four years ago, when patients are MR and TR that has a [INAUDIBLE] valve replacement, I'm sure there was some [INAUDIBLE] the aortic value at that time also. So we do not know much about that. But maybe [INAUDIBLE] you can comment on this.

SPEAKER 2: Yeah, I was able to get the operative report. And actually, this lady had the moderate [INAUDIBLE] at that time. And again, considering that she was in her early 80s, 83 years old, and frail, the surgical team decided to address the valve which were hemodynamically more significant in terms of valvular lesions.

And therefore, they decided to do the mitral and tricuspid valve and just do virtual and follow this aortic valve, which has moderate disease, which is a very reasonable approach knowing that the mortality of a triple valve is significantly higher than a double valve surgery. But 10 years ago, when we didn't have this option, we had to do a triple valve surgery with a mortality greater than 10%. Now we have the options of TAVR.

So in patients with mild to moderate aortic valve disease and other valvular lesions, we discussed with Dr. Sharma and Dr. Kini. And then we decide to address eventually the valve which has a more significant lesion and then address the aortic valve [INAUDIBLE]. Yeah.

SAMIN SHARMA: No I think that's a great approach, particularly now. And there had been trials to answer the question of the moderate aortic stenosis and [INAUDIBLE] you are doing the [INAUDIBLE] surgery. So what is your [INAUDIBLE] the value [INAUDIBLE] 1.1, 1.2, not less than 1. 1.2, 1.3, we can use CABG what would you do for the mitral aortic valve in that situation?

SPEAKER 2: If these are your patients under-- younger age, in their 60s with a life expectancy greater than 10 years, they may address the issue of the aortic valve at the time of surgery. But once the patient, they get in their 70s, and depending on the extent of coronary disease and left ventricular function, again, we discuss with our heart team here. And in some of these patients, we opt to perform the CABG and then, again, eventually down the road perform a TAVR if there is a progression of aortic valve disease.

SAMIN SHARMA: Yeah. Now, and there were some people in late '90s that progression of aortic valve disease post-CABG. The mild to moderate ASU follows them. And we actually have [INAUDIBLE] we need to connect something.

[INAUDIBLE] connect, yeah. So there seems to be some-- if you manipulate the valve during surgery-- just like we do with the coronaries. You know, we put our left catheter in the left main. All the [INAUDIBLE] disease in a few percent of cases, patients come back with a left main disease. But clearly, there after surgery, there may be some progression.

SPEAKER 2: Yes, there is a progression in a significant number of these patients. And again, that's very important to follow up these patients closely every six months to every one year with cellular [INAUDIBLE] geography. And the rate of progression is an average of about 10 millimeter of mercury in terms of the progression of the trans-valvular gradient.

SAMIN SHARMA: Per year.

SPEAKER 2: Per year. Yeah.

SAMIN SHARMA: And clearly, the young age and aortic valve, the renal failure patient will have higher progression.

SPEAKER 2: Yes, yes.

GEORGE DANGAS: Yeah, this is what we can call a staged approach to valvular heart disease treatment. And that's one of the advantages of having the percutaneous options because, you know, you cannot really stage with extensive open heart surgery. But you can use this approach in high risk patient with lives with multiple problems. You just [INAUDIBLE] one after the other sequentially has needed in different points in time.

SPEAKER 2: Yeah

GEORGE DANGAS: That's a good example, this patient.

SAMIN SHARMA: [INAUDIBLE] yeah. OK, now the one question that I know that had been part of a lot of discussion in the live webcast-- do you do a pre-dilate, or do you do a direct value insertion? Just like in the coronary direct, distending versus pre-dilation has kind of established that if you can get your stent there, [INAUDIBLE] not because of calcium, and so it's OK to do a direct distending. So what is your feeling, George? You want to show the-- we are going to show the hemodynamics now.

GEORGE DANGAS: Well, my feeling, and particularly the case with difficult position because of concomitant the mitral valve nearby, would be to try to do a limited dilation in order to facilitate delivery and have a little bit more of a stable position while the valve is deployed. Sometimes we see when you go with a core valve straight in, it may not open symmetrically, or you may have to do a significant post-dilation. Or you know, it may not be exactly the level you wanted in relation to this mitral valve, which is a very important feature in this case. So I would favor here to do a small dilation with probably a 20 balloon.

SAMIN SHARMA: Well, now knowing that there is not much calcium, you are right-- that there are many factors which will say that you need to do it which is very calcium. And they are worried about the sub-valvular apparatus and so on and so forth. In this particular case, I just-- you know, we had a very big meeting, and there were total like 21 international faculty in India. Just like India, you know, London valve, we call it an Indian valve.

And there, a lot of discussion happened on this point. So the major consensus was that if you can put directly, go for it. So what if we try the putting a direct and see what happens?

So again, just to emphasize the point which you said, majority of our cases, we do pre-dilate. But we will start-- I think the overall feeling of the international community is that if you can get the value without pre-dilation, probably OK because clearly, in a non-randomized fashion, anytime balloon, valvuloplasty with TAVR pre or post had been associated high risk stroke rate. There is no question on that fact.

But again, they were not randomized. Maybe those were the cases with the calcific, where we did it. And so-- but definitely, that factor has been the issue. OK, now see, you're watching it at the central.

SPEAKER 1: Now going back to your point, George, regarding the mitral valve, that prior mitral valve, I think during echo, it has been shown that the valve placement is good. The surgical valve, it's not interfering and will not interfere into this TAVR placement. Compared to if they have done a couple of cases where you have the mechanical, the ball in cage in the old--

SAMIN SHARMA: [INAUDIBLE]

SPEAKER 1: We started with valve which is in the, mitral that, we know, will definitely interfere into the TAVR as we are placing it.

SAMIN SHARMA: Take a picture.

SPEAKER 1: One second.

SAMIN SHARMA: So clearly, you brought the catheter to the non-coronary sinus.

SPEAKER 1: Where are we? No, [INAUDIBLE].

SAMIN SHARMA: Angle-wise [INAUDIBLE] good angle.

SPEAKER 3: [INAUDIBLE] to remove [INAUDIBLE].

SAMIN SHARMA: No, but right now looks good, no?

SPEAKER 3: Looks good. Yeah, we remove [INAUDIBLE] from the area.

SPEAKER 1: inject.

SAMIN SHARMA: We are good?

SPEAKER 3: Good.

SAMIN SHARMA: What do you think?

GEORGE DANGAS: Well the angle choice is perfect. You see that the without much strangulation, the new valve is aligned nicely.

SPEAKER 1: OK. We're starting to-- so we are at one, position one. Who's holding the wire?

SPEAKER 3: I am.

SPEAKER 1: OK. OK, stay there. Stay there. Stay there.

SPEAKER 3: You need to [INAUDIBLE].

SPEAKER 1: Inject

SPEAKER 5: Yeah.

SPEAKER 1: OK, that's good.

SAMIN SHARMA: So far OK?

SPEAKER 1: OK. OK, wait--

SAMIN SHARMA: The pace [INAUDIBLE].

SPEAKER 1: Not [INAUDIBLE]. Expand a little bit. [INAUDIBLE] keep going. Yeah. Start pacing, 150.

SPEAKER 3: 150 pacing.

SPEAKER 1: OK. Good go. So now we make sure it anchors.

SPEAKER 3: Good.

SPEAKER 1: Yes.

SPEAKER 3: [INAUDIBLE]

SPEAKER 1: Good. OK, stop.

SPEAKER 3: Good?

SPEAKER 1: Stop pacing.

SPEAKER 4: [INAUDIBLE]

SAMIN SHARMA: Another wild response?

SPEAKER 1: [INAUDIBLE]

SPEAKER 3: Yeah. Right.

SPEAKER 1: Yeah looking good.

SPEAKER 3: Looks good?

SPEAKER 1: OK.

SAMIN SHARMA: Everybody agrees?

GEORGE DANGAS: It looks pretty good.

SAMIN SHARMA: Yeah.

SPEAKER 3: Pretty good.

SAMIN SHARMA: Good.

SPEAKER 1:

SAMIN SHARMA: [INAUDIBLE]

SPEAKER 1: I'm going forward.

SAMIN SHARMA: Yeah.

SPEAKER 1: [INAUDIBLE]

SPEAKER 3: [INAUDIBLE] the wires. Yeah, pull the [INAUDIBLE].

SAMIN SHARMA: Good.

SPEAKER 1: OK, nice. OK, OK, OK, OK. You're pushing too much.

SAMIN SHARMA: [INAUDIBLE] still attached. [INAUDIBLE]

SPEAKER 1: [INAUDIBLE] release.

SPEAKER 3: [INAUDIBLE] no, no, no. See, there [INAUDIBLE].

SAMIN SHARMA: Yeah. Yeah.

SPEAKER 3: Oh, now we're good.

GEORGE DANGAS: That was a good example of attached that was unattached.

SAMIN SHARMA: Yeah.

SPEAKER 3: Yeah. Yeah.

SPEAKER 1: OK, the [INAUDIBLE]

GEORGE DANGAS: There's no parallax. This view was perfect for both positioning as well as deployment. There's parallax in this case.

SPEAKER 1: OK, good. Yeah.

SAMIN SHARMA: The sentinel movement of the device with a sentinel [INAUDIBLE].

GEORGE DANGAS: I don't think that we show movement anywhere.

SAMIN SHARMA: [INAUDIBLE] good. But let's get a pigtail [INAUDIBLE]. No, yeah.

GEORGE DANGAS: So what, with the pigtail in the LV and at the same time we take some echo images?

SAMIN SHARMA: Yeah.

SPEAKER 1: [INAUDIBLE] or no?

SAMIN SHARMA: Yeah, [INAUDIBLE] will do.

SPEAKER 1: OK, ready?

SPEAKER 3: [INAUDIBLE] OK, wait.

SPEAKER 1: Diastolic [INAUDIBLE].

SPEAKER 3: Go.

SAMIN SHARMA: Now if we need to post-dilate, it's a 33 millimeter [INAUDIBLE]. What do you want to post-dilate with?

SPEAKER 3: In case [INAUDIBLE] we can do it 23 [INAUDIBLE].

SAMIN SHARMA: 23 [INAUDIBLE]? That's true.

SPEAKER 3: [INAUDIBLE]

GEORGE DANGAS: Sounds like you [INAUDIBLE] here. At least in this view, it's well-expanded. We don't see that. But of course, we haven't seen the other view.

SPEAKER 3: Yeah.

SPEAKER 1: [INAUDIBLE]

GEORGE DANGAS: [INAUDIBLE] the hemodynamics of the two flushed cathodes [INAUDIBLE] ascending aorta, and we'll see how that looks.

SPEAKER 3: Yeah. The only thing with post-dilation is that [INAUDIBLE] is small. So we'll have to be careful while post-dilating [INAUDIBLE].

SPEAKER 1: [INAUDIBLE]

SAMIN SHARMA: OK, show the-- yeah, good. We are seeing the hemodynamics.

SPEAKER 3: Very good.

SAMIN SHARMA: Actually, the diastolic, what-- it started with what?

SPEAKER 3: 40 [INAUDIBLE].

SPEAKER 2: 50.

SAMIN SHARMA: OK. [INAUDIBLE] AI index is fine. It's more than 25, right? Yeah.

SPEAKER 3: Yeah.

SAMIN SHARMA: OK, so it looks OK. No gradient. And let's do the-- you want to do an aortagram first, or you want to do the echo first?

SPEAKER 1: Hm.

SPEAKER 2: [INAUDIBLE]

SPEAKER 1: OK. We have a pigtail. We'll [INAUDIBLE] difficult. It'll show a lot of AI. [INAUDIBLE] pigtail now.

SAMIN SHARMA: OK, [INAUDIBLE]. Then do the [INAUDIBLE] echo, then [INAUDIBLE]

SPEAKER 1: OK, do the echo.

SAMIN SHARMA: Yeah. OK, we're doing the echo.

SPEAKER 1: Move. Move the--

GEORGE DANGAS: Let's the echo and do the aortagram. In the meantime, while we do the echo images, perhaps Assad can explain the calculation of the index that Dr. Sharma claimed to be above 25.

SPEAKER 2: [INAUDIBLE] minus--

SPEAKER 3: So it's usually LVDP minus the aortic diastolic pressure divided by the LVDP.

SAMIN SHARMA: Systolic pressure.

SPEAKER 3: Systolic pressure, yeah.

SAMIN SHARMA: Multiplied by 100. OK, let's see the echo.

SPEAKER 1: Looks good.

SPEAKER 5: On this view, it looks OK, yes.

SPEAKER 2: So we're [INAUDIBLE].

SPEAKER 5: No [INAUDIBLE] she's coming across the mitral [INAUDIBLE]. So it should not be confused.

SPEAKER 3: [INAUDIBLE]

SAMIN SHARMA: Yeah.

GEORGE DANGAS: It's a little tricky in this view because we see a lot of the [INAUDIBLE].

SPEAKER 5: That's correct.

SPEAKER 1: Go. Let's see short access.

SPEAKER 5: There's no short access in this case.

SPEAKER 1: [INAUDIBLE]

SPEAKER 5: She doesn't have good purse-strings.

SAMIN SHARMA: So that AR index, anything less than 25 is trouble. You need to do something valve is too down, not expended. So value in value, pulling out, pulling down-- and if it is more than 25, it's good. So here, the value is good.

SPEAKER 5: This-- on this, yeah, it looks OK from here.

GEORGE DANGAS: Well, it's interesting. One would say that the diastolic pressure of-- the diastolic pressure of 40 is quite low. But we don't see much evidence of echo AI. The EDP is about 20 or maybe 18.

SAMIN SHARMA: 18, 18. 18 and 45.

SPEAKER 2: So it's around--

SAMIN SHARMA: 425, 26, yeah.

SPEAKER 2: Yeah.

SAMIN SHARMA: Yeah. Good? OK, let's do the aortagram. Yeah. We'll see.

SPEAKER 1: [INAUDIBLE] take out the pigtail.

SPEAKER 3: [INAUDIBLE]

GEORGE DANGAS: Go to hemodynamics.

SAMIN SHARMA: When you're taking the pigtail out, [INAUDIBLE]. Good. Yeah, good? [INAUDIBLE]. Yeah. Ready?

SPEAKER 3: Yeah.

SPEAKER 1: Hold on. It's stuck.

GEORGE DANGAS: Interesting. Where is this pigtail? You can use any of the pigtails, by the way, to [INAUDIBLE].

SAMIN SHARMA: Parallax is out. It's a very good one. Yeah.

GEORGE DANGAS: Parallax-- we never have parallax. This is a very markable.

SPEAKER 2: Inject. Nice.

SAMIN SHARMA: Whoa! All right.

GEORGE DANGAS: Yeah, very good. [INAUDIBLE] so the echo seems to trump the hemodynamic measurements in this case very interestingly.

SAMIN SHARMA: Yeah.

GEORGE DANGAS: Perhaps because the patient did start with a very low diastolic impression anyhow, so maybe we would disqualify the low diastolic pressure from--

SAMIN SHARMA: No, but It's still OK. But remember, it was 45.

GEORGE DANGAS: Yeah.

SAMIN SHARMA: And [INAUDIBLE] were 18. So [INAUDIBLE] were 27.

GEORGE DANGAS: That's what I'm saying. So just a low number-- [INAUDIBLE] 35 is a low number. That's what I'm saying.

But in this case, [INAUDIBLE] started with 50. That's low. Can we go to another view just to see the cage for the-- we seem to be done a bit early anyhow. Can we just stream the [INAUDIBLE] the other view, the [INAUDIBLE] to look at the cage to see how well-expanded is from all--

SPEAKER 1: Actually [INAUDIBLE] the expansion [INAUDIBLE] is better.

GEORGE DANGAS: Yeah I think it's great. I think you can see that this confirms that there is no, I would say, elliptical. It's more circular because it's widely expanded in both views.

SAMIN SHARMA: Yeah.

GEORGE DANGAS: Also great result, and we can get an idea that we're away from the mitral valve both by the echo as well as fluoroscopic view. You can see the three marks that are at the top of the mitral valve stent nonetheless is quite away from the aortic valve.

SAMIN SHARMA: OK, so with that note, we can continue our continuation. And [INAUDIBLE] a great help [INAUDIBLE] expert comments by Dr. [INAUDIBLE]. And now we just go through the anti-thrombotic point next.

So basically, it's the update in anti-thrombotic therapy post-TAVR. Next, so basically, as you know, there's advantage of anti-thrombotic therapy and negative advantage. One is once you do the anti-thrombotic therapy, you're bleeding and mortality.

Now not give anti-thrombotic you don't have, then your [INAUDIBLE] thromboembolism and structural value deterioration. So next, so it has gone through. You do a single antiplatelet therapy next or your double antiplatelet therapy or, next, using an anticoagulation with or without antiplatelet therapy. And that is where this field is evolving.

Next. So basically, next is the recommendation at this time is that DAPT should be considered for first three to six months after TAVI followed by lifelong SAPT in patients who do not need oral anticoagulation. IIa next.

Again, not class one. And then second, is the IIb are SAPT may be considered after TAVI in patients with high bleeding risk while using [INAUDIBLE] TAVI because the European Heart Society, they believe [INAUDIBLE] Europe use TAVI.

We use TAVR. Then the second IIb is oral anticoagulation may be considered for the first three months after surgical implantation of an aortic bioprostheses. So key is, I'll come back to this point without a medical recommendation at the end of my presentation. Next-- now what happens is-- what is the biggest concern of why do we want to use this antiplatelet and anticoagulant?

It's because of the stroke risk. We know acute stroke happens at the time of procedure when we are advancing the device and basically releasing the device. So not only [INAUDIBLE] trauma-- it is the material from the valve also embolizes. And that's where your role of the central device and thus the cerebral protection devices come.

We also know there is a subacute phase [INAUDIBLE] vary whether the perivalvular leak or maybe it's the atrial fibrillation is contributing like two or three days later. You have nothing to do with the TAVR. TAVR is done. But what happens is usually the new onset of Afib.

And then, lastly, that more than 30 days, its patient chronic AFib. But more important [INAUDIBLE]. So they will continue to develop peripheral cerebrovascular various diseases just like any patient with the extensive coronary artery disease have. Next.

So this actually is a very nicely depicted in the patient, clearly, when you do a transcranial recording. And then you can see the majority of issues and problems occur in early phase and then how do you take care of them. And particularly the protection by the [INAUDIBLE] or anticoagulant, it seems to make sense. That is the one which has come to the live discussion at this time.

Next. So now, basically, we also know the bleeding. You use the agent, will cause bleeding. And bleeding is associated with a bad outcome in all these patients whether TAVR or we know for any patient with a coronary artery disease.

Next. So therefore, now the recent presentation of the FRANCE-TAVI registry or the bioprosthetic valve dysfunction that increase the main gradient of more than 10 or new main gradient of 20, and prevalence was 4.5% post-TAVR, next, which we have seen that clearly that those [INAUDIBLE] anti-thrombotic therapy do not develop that leaflet thrombosis as [INAUDIBLE] paper. Next.

And the special deterioration occurs in about 4.5% of cases post-TAVR. So that was the background of the FRANCE-TAVI registry to see that what happens to the patients while on anticoagulants or antiplatelet therapy in a large registry situation. Next.

So this-- we also know that once you have this leaflet thrombus that you start anticoagulation that [INAUDIBLE] and antiplatelet therapy is not the answer. And that actually had been in my field also. And I'm sure, George, you have seen cases too.

When there is a high increase in gradient, we do see the CT angio. We see the restricted [INAUDIBLE] leaflet motion. We start them on anticoagulant.

There's no indication of anticoagulants otherwise, but we give anticoagulant, and the gradient decreases. And that actually have seen repeatedly. One patient, actually, I gave it for 13 months. We stopped.

Four months later, gradient increased again on that particular case, and we are to restart. The how long you should do continue this anticoagulant in situation is not clear, but I think probably one year is the usual time. Next.

So therefore, the anti-thrombotic regime after TAVR from the FRANCE-TAVI registry-- next-- which was presented in the European Society of Cardiology last. That [INAUDIBLE] some patients need various anti-thrombotic therapy for various regions.

Most common is the AFib or new onset AFib. Next. And then if you take-- next-- all the patients, 30% were on antiplatelet therapy alone. 50% were on oral anticoagulation alone, and 25% patients were on both combination oral anticoagulation and antiplatelet therapy. Next.

So basically, the objective of the study was to investigate whether anti-thrombotic treatment influences long-term mortality and early bioprosthetic valve dysfunction, which we defined already 10 millimeter or new 20 millimeter and of explore the independent correlator long term mortality after TAVI. Next.

So basically, these are the last series of patients from the original 13,000 plus cases and we have the follow up mortality, followed by the available in 12,000 patients or 11,500. And for the valvular heart dysfunction, there was about 2,500 patients. Those have appeared echo as a baseline and [INAUDIBLE] two or three year follow up.

Next. And basically what we saw-- next, please. Yeah. So basically, we have various patients who are no anticoagulation and oral anticoagulation-- numbers are shown here-- and various characteristics which we expect that patient with the oral anticoagulation will be more co-morbid conditions. Next.

And so clearly, if you take-- this is an important slide-- that as you can see here, those are oral organization that you say that some of them-- about 8%, 9% of patients-- were on triple therapy. And about 54 had only oral anticoagulation and aspirin.

So [INAUDIBLE] defined separately what oral anticoagulation was because that changed. Sometime they will start in warfarin, then they changed to [INAUDIBLE]. And so [INAUDIBLE] that this is basically, we are-- [INAUDIBLE] comparison is where antiplatelet therapy versus oral anticoagulation plus minus and platelet therapy. Next.

So basically the long term mortality correlate-- next. And very important, what we learn-- anticoagulational discharge. [INAUDIBLE] ratio of 1.18 of mortality at follow up of two to three years. Next.

And others were-- next-- the non-femoral access for TAVR moderate to severe prosthetic regurgitation-- next-- renal failure, AFib, all those which have been reported in the past. But this is the first time the anticoagulation and discharge correlated with long term mortality. Next.

Then you can see here the separation occurs at about three years with the oral anticoagulation, which is in-- yes, it's in green. And survival definitely were lower in patients who were on oral anticoagulation versus not. Next.

So now this is a very important slide that the correlates of bioprosthetic valve dysfunction. So a structural dysfunction, as you can see here-- next-- that oral anticoagulation and discharge-- next-- is associated with lower bioprosthetic valve dysfunction. So very, very important message-- we all knew that prior to our moderate to severe renal failure, non-femoral [INAUDIBLE] prosthesis less than 23 millimeter will have a higher bioprosthetic valve dysfunction.

But this clearly the data of [INAUDIBLE] group from various [INAUDIBLE] and registry now confirmed by this large, steady registry study that oral anticoagulation are preventive of the structural valve dysfunction. But at cost of little higher bleeding and, more importantly, higher mortality.

Next, next, next. So therefore, so it basically happened that-- what do you do in this kind of situation? You use anticoagulation largely because of AFib patients. Next.

And then how do you answer this issue of higher mortality? Next. So we actually-- this is a very nice central figure which those guys have done.

But combining the use of that combination plus a negative point of anticoagulation-- and more important, from valve point of view, it is good. And other point of view, bleeding mortality is the negative point of using anticoagulation. Next.

So then, now we have few trials actually. We can answer this question a little better. The one is the ARTE trial where do you use two antiplatelet therapy or single antiplatelet therapy.

And you can see here. Next. So basically, you see aspirin, clopidogrel versus aspirin. Actually, the aspirin is better compared to combine, although we don't use that.

But this is a small trial of about 300 patients. Next. And it caused lower stroke rate or the non-statistical but definitely lower bleeding with a single antiplatelet therapy. But we have not adopted this.

But this is what that randomized trials showed. Next. Then what about the apixaban versus the vitamin K antagonist? Next.

This is a patient with an AFib. Again, about 270 patients randomized to VKA versus apixaban-- next-- and basically found that apixaban patients did better Earlier [INAUDIBLE] end point, lower vascular complication and stroke compared to vitamin K antagonist.

So you may say we saw a little signal that [INAUDIBLE] may be better compared to warfarin in these patients who require anticoagulation for AFib. Next. So these are the trials where it will be the final answer.

So GALILEO-- and I'll go over a few of them. GALILEO, ATLANTIS, ENVISAGE, POPULAR, AVATAR, and AUREA-- next. So basically, first one is a popular TAVI. This is a 1,000 patient trial and basically will stratify based on whether you NOACs or no NOACs.

So if you have no oral anticoagulation, then you randomize to aspirin or aspirin plus clopidogrel. So this s be the answer. Do you need only one?

And if you need oral anticoagulation, then it will be oral anticoagulation alone or oral anticoagulation with clopidogrel. Why? Because there are some non-randomized data which showed that when in this Afib patient, you used oral anticoagulation alone versus once you add antiplatelet therapy, the outcome improves by adding antiplatelet rather than oral anticoagulation alone. But doing non-randomized, this will be the randomized data.

Next, ENVISAGE-TAVI with the atrial fibrillation patients which will be very important-- that is endoxaban, which is a direct factor 10 inhibitor against vitamin K antagonist. Next. In patient with an Afib, this trial is ongoing with a 2,200 patient randomized one to one warfarin verses endoxaban, these patients all with an Afib.

And they will have a follow up at one month, six months, and 12 month with the [INAUDIBLE] imaging substudy. [INAUDIBLE] 2,200 patients. So George, do you know where we are in the [INAUDIBLE] research trial?

GEORGE DANGAS: We're about 500.

SAMIN SHARMA: Beautiful. Next. Then, ATLANTIS, another trial, which is 15 random patient [INAUDIBLE] after successful TAVI, same-- need for oral anticoagulation versus not, and then they're being randomized to vitamin K or [INAUDIBLE] and vitamin K antagonist versus adaptor [INAUDIBLE] and apixaban about five milligrams twice a day. Next.

Then GALILEO-- this is the GALILEO trial, a major trial, multi-center randomized trial-- next-- with the end point to assess whether our endoxaban-based anticoagulation study following successful TAVI compared to an antiplatelet based strategy is superior in reducing death or first thromboembolic event. And of course, following the other points and inclusion criteria were patient had a successful transfemoral or subclaven TAVI and who did not have an indication for oral anticoagulation. Next.

And these are the primary and secondary endpoints very clearly written. Efficacy and safety point of view-- and the whole idea was that should you give a routine anticoagulation after TAVR in these patients compared to antiplatelet therapy-- so that basically was the concept. Next. And you see this was the trial design-- that after successful TAVI, two to seven days post-TAVR, patients were given rivaroxaban 10 milligram daily plus aspirin 75 to 100 milligram daily.

And other half group, about 1,500 patients, one to one, [INAUDIBLE] continue clopidogrel and aspirin. Now after three months, with the rivaroxaban group, you drop the aspirin. And in the antiplatelet therapy group, you drop the clopidogrel and follow. So now, the trial was completed, 1,500 patients-- next-- completed back in April 2018. And to our surprise and [INAUDIBLE] I would say sadness-- next-- that is the August 2018 data safety monitoring board recommended to halt the study follow up due to safety concern. Now, George [INAUDIBLE], you are the principal investigator, national PI for this trial. Can you comment on it?

GEORGE DANGAS: Yes, indeed. The study, by the way, is going on for several years. We're planning to complete the study towards the end of the year anyhow. The DSMB, based on an interim analysis of adjudicated events, which is a small subset, thought that it's better that we stop in August as opposed to continuing for a few more months.

And we're going to analyze all the data that we get. We'll have a database log for January, I think, and we hope to have the results in-- the final results on all the patients in 2019, either the ACC or the ESE. We can't make any further comment right now because really, we want to avoid any confusion between a fraction of the data adjudicated thus far and the entirety of data that we're going to present finally next year.

SAMIN SHARMA: Right. I mean, I can tell you that I was a big believer in anticoagulation. In these terms. The TAVR patient really came to me as a surprise because I believed-- but only my question was that maybe you needed first three months, not longer than that. In the trial, we gave it for one year.

So I don't know that. But hopefully, we'll know little more. That sum up-- Next.

So then [INAUDIBLE]. Next. So basically, now what are the latest recommendation? Now we get [INAUDIBLE] first update of 2017, ACC/AHA, which now have put-- next-- anticoagulation. Because of this data, the leaflet mobility that give it for three months after TAVR patient.

See that now? This is where I think my thought process [INAUDIBLE] then GALILEO. I think what you need is you need in first three months. And that actually next-- next one-- that you can now use single antiplatelet therapy. Next.

And that is many of these cases, you use single antiplatelet therapy. So that's why I think the two new recommendations which have been made by the latest updated ACCH guideline. Next.

Next, this take-home message, the field of antithrombotic choice post-TAVR continues to evolve with balance between thromboembolic risk and bleeding and mortality. There is evidence that single antiplatelet therapy may suffice in majority, especially in patients with high bleeding risk. Choice of vitamin K antagonist or NOACs if Afib patient post-TAVR seems to favor NOACs in the setting.

Next. Then routine use of oral anticoagulation versus antiplatelet therapy post-TAVR while associated with lower structural valve dysfunction, as we learned from the FRANCE, seems to be associated with higher mortality and bleeding risk. And there was one randomized trial, GALILEO, was terminated, we don't know why, but was terminated due to safety concerns. And the routine use of oral anticoagulation post-TAVR is not segmented until we have more data.

Next. Quickly, we go through our questions. Question number one-- following [INAUDIBLE] the randomized clinical trials of anti-thrombotic therapy post-TAVR except Galileo, ENVISAGE, NOTION, and POPULAR. Next, clearly the NOTION-- NOTION trial was the trial of the low risk TAVR surgery versus TAVR.

Others are anti-platelet. Next, following the randomized trial of different antiplatelet therapy post-TAVR-- ARTE, GALILEO, POPLAR, ATLANTIS. As you know-- next-- ARTE is the antiplatelet therapy. Other ones were the anticoagulant.

Next. Then following are the predictors of higher long term mortality in the FRANCE-TAVI registry except renal failure, NYHA class III to IV, atrial fibrillation, and no oral anti-coalition at discharge. Next. The key was that if you're not on oral anticoagulation, you live longer. So clearly, the answer is D. The fourth-- next one.

SPEAKER 1: Too many questions.

SAMIN SHARMA: The following are for the predictors of the higher structural valve dysfunction in FRANCE-TAVI registry except higher BMI, prior TAVR, oral anticoagulation discharge at presentation, prostheses less than 23 millimeter. Next, clearly, the OAC at discharge had a lower valve dysfunction compared to others which have a higher [INAUDIBLE] valve dysfunction.

Five-- remember, to get the CME credit, you had to have five questions minimum. Which of the following randomized trial of anti-thrombotic therapy post-TAVR has been halted due to safety concern by the data safety monitoring board which spoken about? ATLANTIS, POPULAR, ENVISAGE, and GALILEO-- next. And clearly, answer is D. And now, actually, we can come back to the camera. The [INAUDIBLE] update is what we are done.

SPEAKER 2: So we start by--

SPEAKER 3: Can we show the [INAUDIBLE], the [INAUDIBLE]? Yeah, so the way we start doing it is we have this wire, which is up in [INAUDIBLE] safety wire which we put at the start. We take a [INAUDIBLE] a picture DSA of the bifurcation of the distal aorta to make sure there's no dissection there before we go up and over.

SPEAKER 1: [INAUDIBLE]

SPEAKER 3: Then we close it. This is a picture.

There were still some [INAUDIBLE]. We did slight massage with a 7-0 40 balloon. And this was the final picture. There was no real ooze or bleeding at the end. And we closed the other side with a [INAUDIBLE].

SPEAKER 1: Beautiful look at it. Like no procedure has been done.

SAMIN SHARMA: Look at the groin. So this is actually going through our head way towards the day TAVI, same day TAVR. That's what they have been using in many places like from Canada.

Of course, it would be a big issue here. And [INAUDIBLE] that clearly, the vascular complications have really declined with a very meticulous technique. But George, it's all--

GEORGE DANGAS: No, this is a great result, particularly the final comments regarding the possibility to migrate towards [INAUDIBLE] predictable next day, next morning discharge, and then see if we can select even patients for same day-- obviously, the first cases of the day for this reason.

SAMIN SHARMA: Same day.

GEORGE DANGAS: It's interesting to-- it's interesting to even discuss it. I remember it was-- that was a case from Canada reported maybe a few years ago, more like an anecdote with even a picture of the patient upon discharge. And it's interesting that more than a few centers now start doing something like that. Anyhow, this was a great demonstration, a very complex case made simple by the heart team here at Mount Sinai.

We definitely think the surgeons for their active participation as well. Well, thank you also all for joining us today on this exciting case. And sending a few questions I pass along into the operators.

This case will be at the CCC Live Cases [INAUDIBLE] related [INAUDIBLE] in its entirety, including the questions and answers that Dr. Sharma very nicely conducted. Structure life case reviews and presentations occur every other month, every two months, on a Tuesday at 9:00 AM. So the next trial will be Tuesday, November 13 at 9:00 AM. And I would like to thank you for joining us today at Mount Sinai.