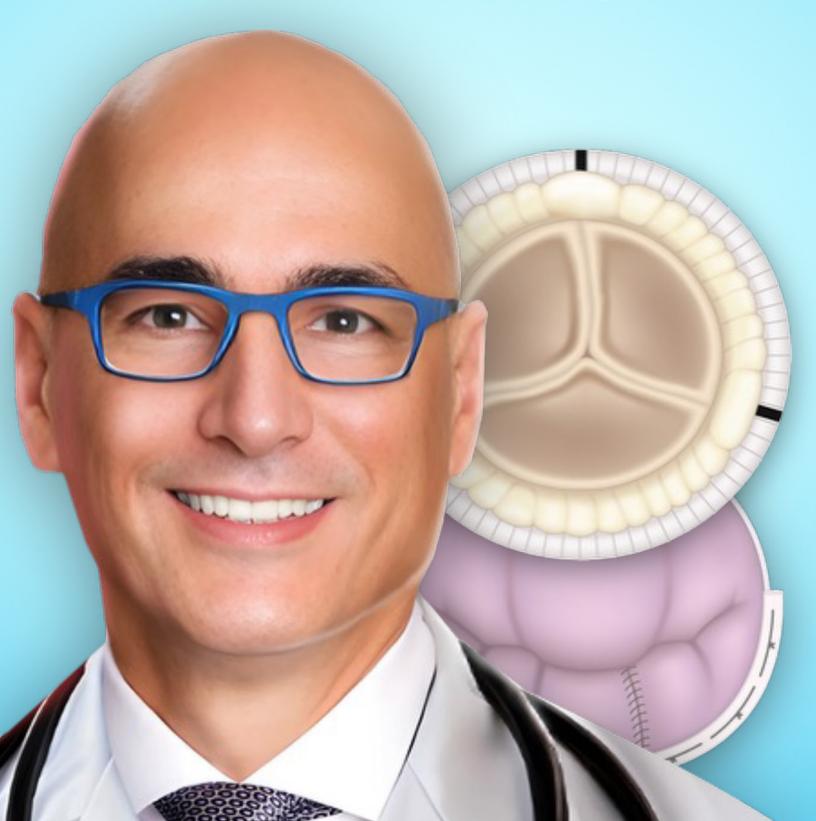
ASK DR. GERDISCH ANYTHING!

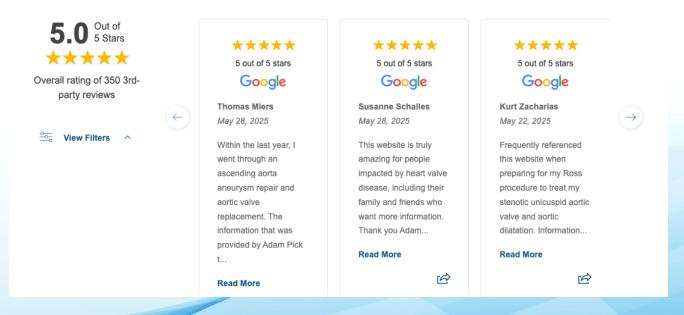


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Featured Speakers



Dr. Marc Gerdisch
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Learn More.



Please note: A complimentary video playback of this eBook is now available on YouTube at this link.

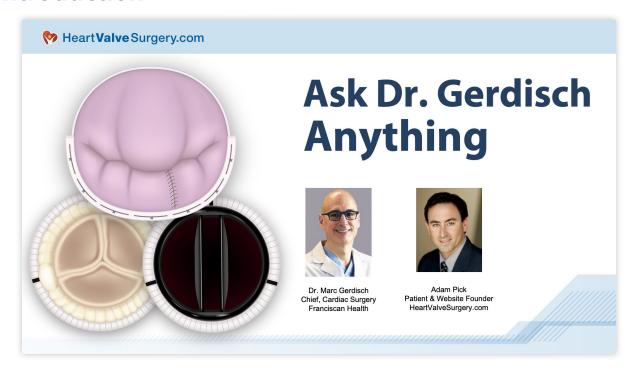


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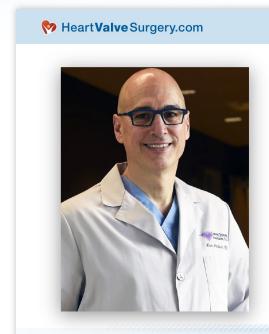
Introduction



Adam Pick: Hi, everybody, my name is Adam Pick, and I'd like to welcome you to the webinar titled, "Ask Dr. Gerdisch Anything". If I have yet to meet you, I'm the patient who started HeartValveSurgery.com all the way back in 2006. The mission of our website is really simple; we want to educate and empower patients just like you. This webinar, which has had over 400 registrations from patients in countries all over the world was designed to support that mission.

Now, throughout the webinar, you're going to be in what's known as "listen-only" mode, but I'd encourage you to submit your questions, as many of your questions as possible, in the control panel that's on your screen. The agenda for today is very simple; I'm going to introduce our featured speaker and then we are going to ask Dr. Gerdisch anything. I'm going to conclude this session by asking you to complete a very quick five-question survey.





Dr. Marc Gerdisch

- Chief of Cardiac Surgery, Franciscan Health, Indianapolis, Indiana
- Performed 7,000 cardiac procedures and 5,000 heart valve procedures
- Minimally-invasive and rapid recovery specialist

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When it comes to our featured speaker, I am honored and humbled that he is taking time away from his very busy practice in Indianapolis, Indiana. Who is he? His name is Dr. Mark Gerdisch. He's the chief of cardiac surgery at Franciscan Health in Indianapolis, Indiana. He has performed not 1,000 or 2,000 but 7,000 cardiac procedures, of which 5,000 have involved some form of heart valve repair or heart valve replacement.

When it comes to his specialties, he is a minimally invasive specialist and a rapid recovery expert; we're going to talk about that today. Another bullet point that I would put on this slide is Dr. Gerdisch is an innovator in the field of heart valve research.





How committed is Dr. Gerdisch to the field of heart valve disease? Well, if you were to look at his car, you would see the license plate reads, "HRT VALV". That's right; his license plate is "heart valve". It's one thing to have it on your license plate, but it's another thing to do what? To help people.

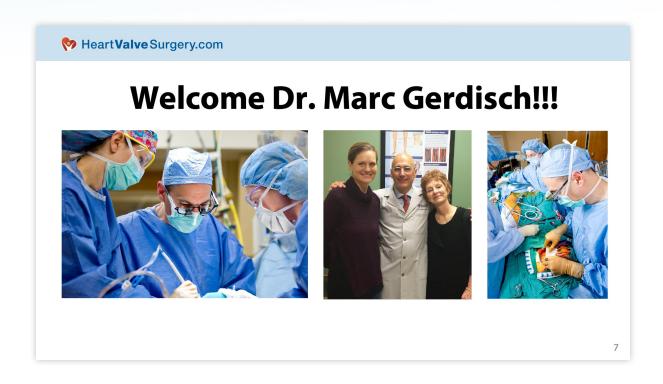


Dr. Gerdisch has helped a lot of people in our community. He has over 141 patient reviews. He's helped folks including Todd Runnenbalm and Matt Schutte and Linda Kincaid, Janelle Hurst, and Dan Rhoden. His patients go what I call "Ga-Ga for Gerdisch". You can see they even put together t-shirts for the tennis courts that say "Powered by Team Gerdisch."





We can talk about his accolades; we can talk about his research; we can talk about his achievements. This is something I want to share with you. These are patients of Dr. Gerdisch's who are going through recovery. Some on the left you'll see are early in that recovery -- in the hospital. Then, you'll see you've got some patients like Matt who's hitting a baseball in his third week of recovery. I want to welcome Dr. Gerdisch to our webinar, and I also want to thank him.



Together, Dr. Gerdisch and I have been on a nearly 15-year journey of education and empowerment, and Dr. Gerdisch, I can't thank you enough for all the support you have given our community, so thanks so much for being with us today.

Dr. Gerdisch: Thank you, Adam, and congratulations for having this kind of level of impact. Has it really been 15 years that we've known each other?

Adam Pick: It has.

Dr. Gerdisch: Oh, my, it goes really quickly, doesn't it? But yeah, it's fantastic. Yeah, my shoutout back to the community for everybody getting on and learning as much as they can and helping us sustain knowledge at the level outside of our operating rooms and academia, so good.



Rapid Recovery Protocol 2.0



Adam Pick: Let's kick it off with a great question right to your specialty, which is all about rapid recovery protocols. Tom asks, "Are there any new updates on Dr. Gerdisch's rapid recovery protocol?" On the left, I know you've been doing some work in-operating room ventilator removal, and then I know there is some real exciting stuff about a new tube that's helping. Can you talk about that for Tom?

Dr. Gerdisch: Sure, so yeah, these are both kind of interesting representative pictures in the sense that that tube on the right is just a chest tube. One of the

things that kind of drove me nuts for a long time was that for 70 years, we'd used the same archaic chest tubes. We'd use these plastic tubes to drain the chest and never really knew if we were fully clearing the chest and we didn't have a mechanism for keeping them patent. When it was studied, more than two-thirds, close to 80% of chest tubes were clotting. For all these years, we've just kind of done this kind of mechanical manipulation of them and fretted over them.

Finally, a team came out with a tube that has a mechanical mechanism for clearing the fluid. So there's a little wire that goes up through the tube, has a little spiral at the end of it. We're always sure that we're getting the chest tube, that the chest tube is open. Well, it sounds like a simple thing, and it might not sound as important, but it's incredibly important because when people retain any blood products in their chest. Number one, you don't know that the blood is there and could be causing trouble right after surgery. Number two, if it stays there for a while, it causes inflammation; it causes fluid to accumulate. It makes a patient feel unwell, inflammation.

With this tube, when we brought it on, because as we do with everything when we bring a new device on, we study it. So we studied this tube for a year, collected continuous data, and compared it to another year of similar patients done by the same surgeons, the same operations in the same quantities, and it was absolutely remarkable what we found with decreases. We had a one-day length of stay decrease; we had a huge savings in blood transfusions. We had less overall drainage. We think that's because when you keep the blood out of the chest, that promotes healing and closure of small vessels and diminishes the inflammation.



As a consequence of all that and decrease in perioperative atrial fibrillation as well, but as a consequence of all that, when we recognize that with this tube we were very confident about whether there was any continued bleeding, and we knew that we were going to be be able to manage the fluid in the chest. It was one of the things that contributed onto the thing on the left, which is as many people know, last year we published a paper showing we could do sternotomy heart surgery, not just in minimally-invasive cases, which forever we've not had to use narcotics because of our intercostal block but sternotomy patients because of the way we manage the sternum, we don't use narcotics anymore.

At the same time, we eliminated sternal precautions. In other words, people can use their arms immediately after surgery, get up and down from a chair, up and down from the toilet, up and out of bed, which also meant they went home. Essentially, everybody goes home instead of an extended care facility.

Then, the next step for us was to get the tube out of their mouth, because people don't like to wake up with that. So now, we have a median time to extubation of zero hours, which means the majority of our patients have the tube out of their mouth. Doesn't matter if it's a sternotomy or minimally invasive, the tube is out before they leave the operating room because we've kind of equalized the experience.

For me, it's always kind of been well, okay, I love doing minimally invasive surgery, but I can't do that for everybody. What do I do for the triple valve and Maze procedure patient? What do I do for that patient?

We figured it out, and so we marched toward this process where everybody looks the same. Median time to extubation, zero hours; you can use your arms right away; you can drive when you feel like it.

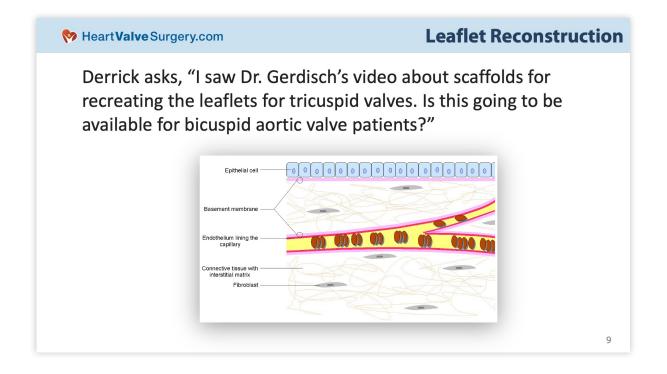
We don't have any restrictions on that. So those are the things. Basically what we did is we built on what we've already accomplished; we added a little bit more technology. Then recognizing the opportunities, we took full advantage of them. The other thing is many people recover better and faster if you can get the tube out of their mouth and get the up sitting, walking immediately. So all those things have kind of happened as a natural progression from the work we were already doing.

Adam Pick: Dr. Gerdisch, as a patient who woke up after my own heart valve surgery not knowing there was going to be a ventilator tube in my body, that was incredibly uncomfortable. I want to thank you and your team; I know this takes a village to come up with this research and tests and retests, so thanks for everything you're doing to make the experience for a patient much more comfortable.

Dr. Gerdisch: It's very much a team effort.



Cardiac Innovation: Leaflet Reconstruction Using Scaffolds



Adam Pick: Let's move on to another passion of yours that will come out in Derrick's question, which is, "I saw Dr. Gerdisch's videos about scaffolds for recreating the leaflets for tricuspid valuves. Is this going to be available for bicuspid aortic valve patients?"

Dr. Gerdisch: Right, so we've been kind of knocking on this door for quite a long time. As you know, we are closing in on the end of our FDA trial with the tricuspid, regenerative tricuspid valve, which is super exciting for us. We want to eventually traverse into the other valves. If I kind of give you hopefully only two minutes of this because I know we have a lot of questions, but this is a passion of mine. I think this is a field that we need to stay on and focus on, even though engineering in valve surgery and valve technology kind of takes us in a different direction in



general, which is the next TAVR or the next surgical valve.

Those are constructs. We have to think about what their fabrication is. So presently, Dr. Yakoub, one of the most famous heart surgeons on the planet. He's not doing heart surgery any more but probably one of the – may have done more heart surgeries than anybody else, who's based in London. He actually has a valve that is considered to be a scaffold that will regenerate tissue that is going into some patients right now. I know some about that fabrication; I think it's super interesting and unique.

I was just in Zurich. While I was there, I visited Berlin Heart which has a tissue engineering lab in Zurich and I looked at the work that they're doing. They're actually culturing, essentially culturing human extracellular matrix, the material that we use from the pig, and then they're decellularizing it and making constructs out of it. In their bioreactors, they're adjusting the fabrication of these constructs. Then, there's the work we're doing where we take an adaptive matrix, a matrix from the small bowel of a pig, and then we completely decellularize it and we use that as the framework for the stem cells.

So those are the pathways that are being run down. When will we end up with an aortic valve? Well, I would take you on one other tangent. There have been a few cases where the aorta of the same human being, the wall of the aorta was used to rebuild leaflets, like entire leaflets. Now, I've done a few cases where I've used it as a patch on aortic leaflets. I have not replaced entire valves, but it has been done. So we're going to see where that takes us. That's really exciting. It's your own tissue, and what are you trying to achieve with that? You're trying to choose something better than the current tissue valuves, which in a sense, this shouldn't be too hard because those are tanned, glutaraldehyde treated, dead tissue whereas we'd have a living substitute.



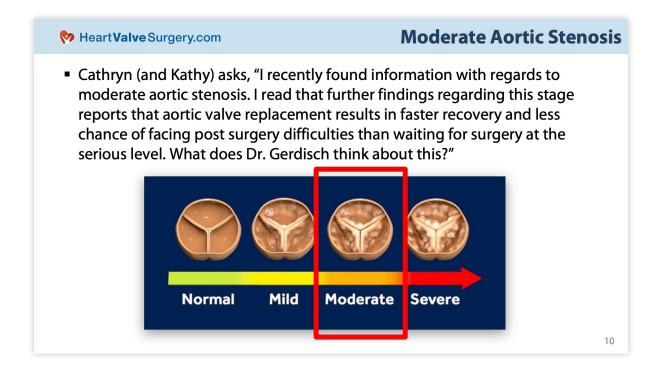
I do think we're going to get there. I think we'll get to the left side of the heart. We'll probably get there with a version of our scaffold. I think the folks in Zurich will have something. I think that it'll be interesting to see what Dr. Yakoub's valve does. Meanwhile, people are still kind of looking at engineering things in the operating room using the patient's own tissue. It might be a while yet, but I think we're going to get there.

Adam Pick: Dr. Gerdisch, I want to just commend you for the ongoing research because you might not remember this; one of the first videos we ever did at STS in San Diego in 2011 was about extracellular matrix. So, for everybody on the line, Dr. Gerdisch has been working on this for how long now, Dr. Gerdisch?

Dr. Gerdisch: Yeah right, at least 15 years.



Moderate Aortic Stenosis Risks



Adam Pick: We received a lot of questions about moderate aortic stenosis. Katherine, and Cathy, and someone else asked about the same thing. "I recently found information with regards to moderate aortic stenosis. I read that further findings regarding this stage reports that an aortic valve replacement results in faster recovery and less change of facing post-surgery difficulties than waiting for surgery at the serious level. What does Dr. Gerdisch think about this?"

Dr. Gerdisch: It's such a good question and unfortunately, I can spend the whole hour on this, but I'm going to try to condense it because this is really important. That picture is a good one because it's like a sliding scale. And we have to think of that sliding scale both with respect to the actual pathology of the value, the patient's symptoms, and the physiologic consequences for the patient, and that last one might be the most important.



So what we have right now, and it's not for moderate stenosis; it's for severe asymptomatic. We had two surgical studies which were, I think they're called Recovery and Avatar. In both of those surgical studies, when patients had their aortic valve replaced for asymptomatic severe aortic stenosis, they had concrete improvement in their outcomes. That had to do with heart function and survival.

Now, we recently have published a similar study which is called Early TAVR, which is for the SAPIEN valve, which is a transcatheter valve, and that is for asymptomatic severe aortic stenosis. The one thing that they had that was positive was they had less readmissions after having the transcatheter valve. They didn't have better survival; they didn't have less strokes. They did have, not statistically significantly, but they did have less admissions and they had better quality of life scores. That's a little bit of a slippery slope.

I'm going to tell you why that's a slippery slope, because if you have something done to you, you tend to feel like you're supposed to feel better. Some of those quality of life scores can be a little "iffy". I mean, I think that's true even if we look at the recent Triluminate study for the tricuspid valve where patients get a clip for their tricuspid valve or don't get a clip. The ones that had something done thought they felt better.

One of the important things when we look at these studies and we scrutinize what's going on is we think about two things. Number one, is there any possibility that the fact that they're feeling better has something to do with having had a procedure where the other person didn't? Is there something to do with the way they're managed medically after that, even though it's standard of care in both groups? I'm not saying that's what happened; I'm saying we have to think about that. If we want to really understand it, we need to look at the heart muscle itself.

When we talk about aortic stenosis, I have seen patients with severe aortic stenosis who have beautiful left ventricles that relax perfectly. They're not thickened; the patient's asymptomatic. They're able to do all their normal things. They don't have changes in what we call global strain. They don't have evidence of what we know is the result of histopathic changes in the muscle. If you don't see those things, then it's probably not an advantage to jumping in there. But if we're sophisticated and nuanced about the way we look at it when the patient isn't having symptoms but they have an elevated gradient and we see that the ventricle has started to thicken or there's evidence of fibrosis or the left atrium's enlarged or they're having atrial fibrillation or something's going on, then we should be more serious about it.

I think what this is for us is a call to be very sophisticated and nuanced, and the way that we evaluate and judge the severity. There's another animal out there that's called low-flow low-gradient severe aortic stenosis. Well, what is that? It's a low-gradient severe aortic stenosis. In other words, the gradient doesn't get up to 40 but maybe it's 25. We call it low flow because the stroke volume index may be diminished and the amount of blood that gets pushed through the valve. Well, it becomes very nuanced to understand what is really driving that. Is it changes in ventricular performance or function? Are there other characteristics of the heart that contribute to that?

So I'm going to finish by just saying no, moderate aortic stenosis is not supposed to be treated at this point. Yes, severe asymptomatic even – we learned this in mitral valve regurgitation, right? Severe asymptomatic aortic stenosis that's generally severe should definitely be given consideration for treatment. Again, a nuanced approach to the patient, what the real lack of symptoms are, and how their ventricle is performing. Sometimes people are asymptomatic. You put them on a treadmill, they get short of breath.



Follow-Up Echocardiograms After Surgical Aortic Valve Replacement

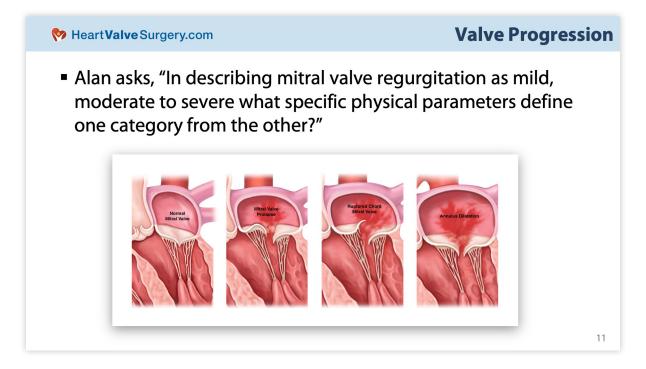
Adam Pick: Dr. Gerdisch, we're going to go right to Duncan's question that just came in. I'm hoping this is going to be a quick one because we're going to get to another question about mitral regurgitation. Duncan asks, "How often should I have a follow-up echo after surgical aortic valve replacement?"

Dr. Gerdisch: It depends on if you had a tissue or mechanical valve. It also depends if you're having any symptoms and who your cardiologist is and what your heart looks like. So the simple answer is that with a tissue valve, there's a little bit lower threshold for repeating echocardiograms. The standard, the minimum, the requirement is that every five years, you have an echocardiogram unless you're symptomatic. You get one every year anyway just because they can and they want to see what's going on with the valve, any changes in anything.

For a mechanical valve, last I checked, and that was probably a decade again, but because we did all the studies with the On-X valve, there's no actual clear-cut indication to have an echocardiogram after you had a mechanical aortic valve replacement because it doesn't change. The valve never changes. So when I did all the studies with the On-X valve, one of the things I did was I did a five-year follow-up to prove that the valve looked exactly the same and nothing was happening. I did that again; I did that twice. It's important to recognize that mechanical valves don't change so if the patient's not having any symptoms or no issues, there's really no reason to do an echocardiogram. It's okay to get one, especially if someone is looking at something. Maybe you had some changes in your heart before you had the aortic valve replaced; you want to look at those other changes. The valve itself should be a non-issue unless it's starting to deteriorate.



Physical Parameters of Mitral Valve Disease Progression



Adam Pick: We have this question from Allen that came in, "In describing mitral valve regurgitation as mild, moderate, to severe, what specific physical parameters define one category from the other?"

It's mitral valve regurgitation. So again, going to go down a little bit of a rabbit

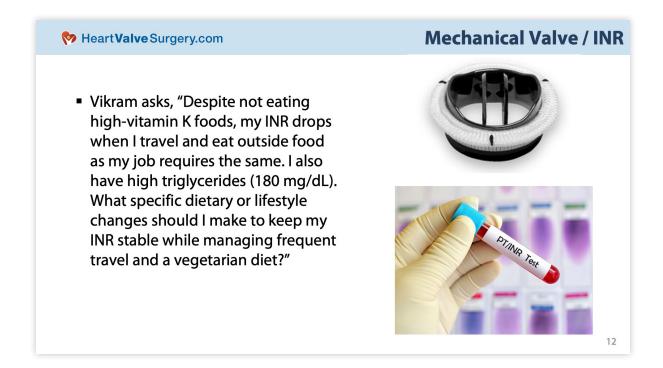


hole because you can measure the same person twice and get different numbers. There are two reasons for that; it's the anatomy of the valve and their volume loading or stress at the time on the heart. Barring that, when we see a regurgitant volume that exceeds 50 ccs, we start to think of it in terms of severe. We definitely think of it in terms of severe when it hits 60. When we see a regurgitant volume of about 40, we call that moderate. When we see something below 30, we call that mild. Anything below that is insignificant.

It's just a matter of volume of regurgitation. Again, keep in mind that will change based on the volume loading of the patient, whether their blood pressure is elevated at the time, and how the ventricle's performing at that given moment in time. I think that's very important in the mitral, too, and more important than tricuspid valve.



Mechanical Valve Replacement and INR Management



Adam Pick: Great. Let's go back now over to the discussion about mechanical valves, because this is a lifestyle question. For those folks who, along with their physician, believe that getting a mechanical valve is their way to go. Vikram asks, "Despite not eating high vitamin K foods, my INR drops when I travel and eat outside food as my job requires the same. I also have high triglycerides. What specific dietary or lifestyle changes should I make to keep my INR stable while managing frequent travel and a vegetarian diet?"

Dr. Gerdisch: One of the questions I would ask Vikram is how he checks that, if he's got home monitoring and whether he's managing it that way because I think that becomes important. People have variability. The home monitoring is very good. I mean, most of my patients use it, but it is a little bit of a relative management strategy in the sense that it might not be exactly the same as the lab, but it will vary in the same way. Once you kind of know your spot, you keep it there with your home monitoring.

I'm going to jump to the triglycerides because the triglycerides is very important and you should be getting specific therapy for that. With respect to nutritional management, without getting too into detail about it, I think it's important that people recognize that the triglycerides are a signal and that fatty acid balance and lipid management, a lot of that can be managed well with supplements and with your diet. Thinking a little bit in terms of those is an important issue for him.

Now why does the vitamin K issue, why does that happen? Why is his INR changing when he eats outside foods? Well, I mean, any time you make – if that's a substantial shift from your normal diet, then that can impact your INR level. It's partly because of the vitamin K; it's also partly just because there are certain foods that interact with your vitamin K processing and in your liver, too. You would want to be thinking in terms of maybe just trying to achieve that consistency by somehow keeping your vegetarian diet alive and well while you're traveling. This becomes a really important aspect of how you determine the impact on your life outside of the valve. I mean, I have friends who are vegetarian; I have lots of friends who are vegetarian. When we travel, we just figure it out.



So I think Vikram, my advice would be don't eat outside the food; the vegetarian diet is perfectly good for you. Just make sure you get a good balance and enough protein. Then I would attack those triglycerides and look a little bit at fatty acid management. Some of the, for example, fish oil pills, some are very high-quality. Then recently, I started to look at Fatty-15, which is a specific dietary supplement that looks like it has a nice tonal balance for triglycerides and cholesterol levels. These are all things you can work with your physician on. That would be my answer.



Warfarin Substitutes for Mechanical Valves

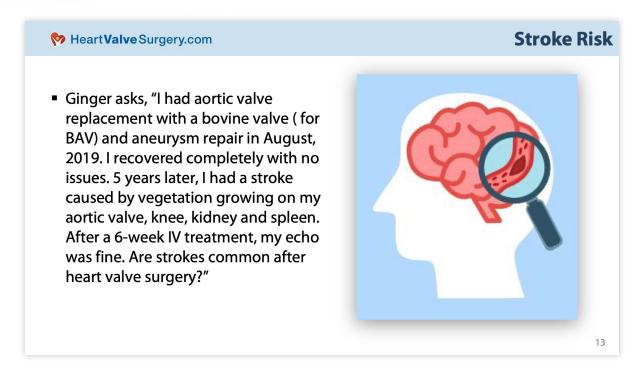
Adam Pick: Let's stick with mechanical valves because we get this question coming in live from Lawrence, which is, "When will there be a substitute for warfarin?"

Dr. Gerdisch: Yeah, it's unfortunate that warfarin is as good as it is at what it does, because it does have to be managed. So we did do a study with Eliquis, and it worked okay, but it wasn't nearly as good as coumadin, so we stopped the study early. In other words, we were still staying below what we see as the recommendations of the overarching authorities that say how many events you should have with a device and we were still below those, but we weren't nearly as good as we were with warfarin. So that's why even with the On-X valve, in my opinion, the most advanced mechanical valve technology on the planet, we weren't able to make that switch.

There is another study going on right now in Asia with a different blood thinner. I don't know how well that's going to translate into the rest of the planet, but that is an ongoing study. So my opinion is we're going to find one, but it's going to be a while yet, and these studies take a long time. It takes at least a few years to understand if we've made the right move with the data. So I think it's going to happen; I just can't give you a timeline on it. In the meantime, as much as warfarin gets a bad rap, it's a darn good drug and we do have ways to manage it and keep it under nice control tightly, so that's where we are.



Stroke Risks



Adam Pick: Let's move over to a discussion that comes up all of the time, which is stroke. Ginger asked, "I had an aortic valve replacement with a bovine valve for bicuspid aortic valve and aneurysm repair in 2019. I recovered completely with no issues and then, five years later, I had a stroke called by vegetation growing on my aortic valve, knee, kidney and spleen. After a six-week IV treatment, my echo was fine. Are strokes common after heart valve surgery?"

Dr. Gerdisch: This is a complicated scenario. Most likely, this valve was infected. It was a vegetation; she received six weeks of IV treatment, meaning antibiotics, I'm sure. Now, the valve looks clean. Often, the majority of the time, actually, once you have a substantial vegetation or embolize from a vegetation, the valve can't be cleaned by antibiotics. In a sense, she's fortunate she got a valve that still works okay. She's finished with her antibiotic therapy.

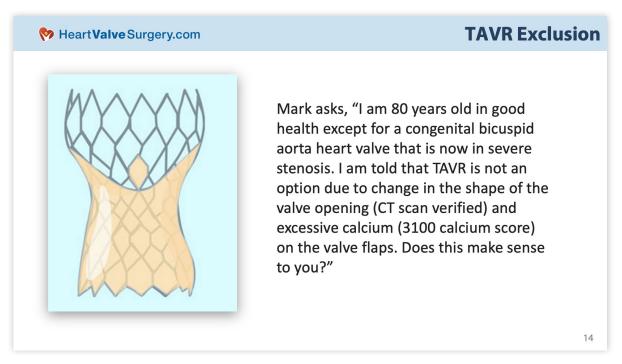


There are two aspects of this. One is how common are they after heart valve surgery; they're not very common. If we look at the overall data, in the first year after any valve surgery, whether valve replacement and quite honestly, it's whether it's transcatheter or surgical. It falls in somewhere between 1% and 4%. I mean, that's a real number, and it's a number obviously to be concerned about. The reality of this particular situation is that we don't know what the construct of that valve looks like now that it's had an infection on it and infection's gone. The question would be are there areas on that valve that are still going to be sensitive to and vulnerable to developing clot or being infected again or whatever. So think that it would depend a little bit on what the anti-coagulation strategy is going forward and which some folks might lean toward at least a low dose of actual anti-coagulant in this person who's already suffered an event.

Fortunately, it's not frequent. Unfortunately, you suffered one. When you say growing in my aortic valve, knee, kidney, and spleen, that sounds to me like probably embolization went to the brain, to the kidney, and the spleen, as well. Maybe there was some source in the body, maybe the knee, where the infection started and they cleaned that up, too; I'm not sure. But that's how I would interpret that.



Transcatheter Aortic Valve Replacement (TAVR) Exclusion Criteria



Adam Pick: Let's talk about one of the biggest revolutions in valve therapy, which is TAVR. We've seen – I know you probably have more data than I do, but I saw it's gone from about 4,000 cases in 2012 to over 100,000 cases in 2023, Dr. Gerdisch, a lot more inclusion for this device. We have a question from Mark about exclusion criteria. He says, "I'm 80 years old in good health except for a congenital bicuspid aorta heart valve that is now in severe stenosis. I'm told that TAVR is not an option due to the change in the shape of the valve opening; CT scan verified, and excessive calcium, a 3100 spore on the valve flaps. Does this make sense to you?"



Dr. Gerdisch: Makes a lot of sense to me. It tells me that the folks that are taking care of you are paying attention to the actual guidelines and that they are interpreting the studies properly. This is actually a really important issue on a number of levels. First of all, 80 years old, okay, fine, otherwise in good health. This is a patient that we typically would do a minimally-invasive surgical aortic valve replacement for and I agree. With bicuspid aortic valves, there are some that are nicely amenable to a transcatheter valve. They're the ones that look a little bit more like a trileaflet valve and/or don't have a lot of calcium in what we call the raphe'ing, which is the fused part. When you look at a bicuspid valve, it looks like two leaflets got stuck together; they're fused together. Then there's one other more generous leaflet that's soft and normal. When they become diseased, the part that's stuck together tends to get more heavily calcified. That is called the raphe. When it's very calcified, if you blow a balloon up in there or a valve up in there – and this is a 3100 calcium score. Anything over 3,000, we'd be very concerned about. You can actually push that raphe through the wall of the aorta.

The other issue is when a bicuspid valve opens, it doesn't open circular; it opens as an ellipse. You're putting a circular device in there. You can't change the shape of the annulus like we can surgically. So you end up with gaps on each side that result in leaks, so we know there are more leaks. We know that there is a higher chance of rupture or embolization from the valve, especially with high calcium scores. So even if you look at the AHA and ACC guidelines, the guidelines say that for bicuspid valves, it should only be for high-risk patients who are very suitable, whose anatomy is very suitable. Otherwise, they should have an operation.



So again, we would do a minimally-invasive surgical aortic valve replacement for this patient. His team is thinking clearly on this. Recently, there's been some publication looking at low-risk patients, real-world data for transcatheter valves. Now, we all know with the enthusiasm of transcatheter valves, they've migrated down into younger people, lower risk people. What we're seeing in the real-world data that was published is the outcomes aren't as quite as good as they were for the studies. It's especially true in the bicuspid valves.

This gentleman, Mark made it to 80 with his bicuspid valve. A lot of people show up sooner with bicuspid valves, so a lot of the people that we treat who are younger are bicuspid because bicuspid valves are abnormal from birth. They tend to go through the degenerative process a little bit sooner than a trileaflet valve. I covered a lot of territory there because it's important for people to recognize specifically to bicuspid valves that we have to be very thoughtful and in this person's case, this team is making the right decision.



Rise in TAVR Explant Procedures

Adam Pick: Dr. Gerdisch, I talked about the huge swell in TAVR procedures. I also want to just ensure that all the patients on the line know that at the same time, we're also seeing an increase in the amount of TAVR explants that are happening as well. So I think this conversation of inclusion and exclusion for this minimally invasive technique is really important for the folks on the line. Would you agree, or can you comment on that?

Dr. Gerdisch: Very important is the transcatheter valves are a fabulous addition to our armamentarium. It's really changed the context of management for sick or older people for sure, and like I said, it has migrated down into some of the younger and lower risk patients. This all becomes part of the strategy of lifetime management. Having taken out of a bunch of these transcatheter valves, it's not easy; it's not terrible. It's not easy, and the patient's having another operation they may not have had to have otherwise. So they're being put at risk.

So there are multiple levels to this. First, is the notion that you would put a transcatheter valve in a younger, healthier person puts them at risk, obviously, of need – they're going to need another operation. The next operation is probably going to be a surgical valve. TAVR-in-TAVR is okay but it's not really the ideal procedure. We also know even folks who – kind of the groundswell that went into tissue aortic valves is also kind of come around a little bit because folks were being told well, we're going to put this valve in you now and later, we can put a transcatheter valve inside your valve later. Number one, it's not always



true that we can do that. Number two, the survival after a valve-in-valve, in other words a transcatheter valve inside a failed surgical valve, is not as good as the survival of redo valve surgery. So if your tissue valve wears out, right now as the data stands, it doesn't look like there's an advantage of getting the valve-in-valve. That's not going to be true for everybody. Some older sicker folks, you get into your late 80s or somethings, sure, it makes sense; go to valve-in-valve.

The outcomes in the other folks – and it's not subtle, although they had to do match sets. It's not a randomized study, but the difference is so dramatic that even if the difference is half of what we saw, it's a serious problem. It's just a matter of just being thoughtful, just like this team was thoughtful about Mark. We can do a transcatheter valve, but it might leak. We have this risk of rupture. Someone else may be a young person; yeah, we can do a transcatheter valve, but what's the next step?

Taking them out is increasing quickly because we have so many of them out there. People aren't making mistakes; it's just that there's enthusiasm. There's data that suggests that the valves are functioning well. Patients don't want to have surgery, but I think also, as you know, I've shown earlier with our recovery protocols with minimally invasive surgery, we've really taken a lot of the sting out of the operation. I mean, it's just not what it used to be as far as magnitude of the operation, the recovery, the time in the hospital, the time not being busy and able to carry out your normal activities. Lot of stuff there, right? This goes to who's on your team.



Transcatheter Mitral Regurgitation Treatment (TMVR)



Adam Pick: Let's shift gears over to mitral regurgitation treatment. Cathy asks, "What current and upcoming transcatheter treatment options are there for a healthy, active woman in her 70s with severe mitral regurgitation with a history of aortic valve replacement done 32 years ago and a history of rheumatic heart disease?"

Dr. Gerdisch: Wow, yeah, so this is a really interesting case, especially if the mitral valve is rheumatic. Just had a person recently. We see this; we still actually see a fair



amount of rheumatic heart disease. The question is about the transcatheter devices, so let's start at the end, which is transcatheter devices, we now have one FDA-approved transcatheter device for mitral valve replacement. It's the Tendyne device by Abbott. I think it's in your pictures here, maybe. Yeah, it's the top one on the left. It is put in through the tip of the heart through a little incision on the left side. It is cleared for heavily calcified mitral valves, so a valve that might be considered very high-risk for surgery, whereas we might take that calcium out to replace the valve. Some folks aren't comfortable with that, and sometimes it is quite challenging. It's a nice answer, I think, for people who might be very high risk for surgery.

The drawback will be – for example, I have a lady tomorrow. She's 89 years old. She has a very calcified mitral valve, and the opening of that valve is very small because the calcium has impinged on the opening of that valve. So when she has the surgery, I have to take all that calcium out to put the new valve in because I need room. If you have this, the Tendyne is a self-expanding device. It's only going to fill the space in the middle of that calcified valve. So for example, this lady tomorrow, she would not be a candidate for this because you can't possibly make the valve big enough inside that tiny mitral valve that she has.

Another person, though, might have a lot of calcium and a valve that leaks and the valve's pretty round and you got a nice size hold there and the leaflets will get out of the way. They're high-risk, might be a high-risk patient, and so the Tendyne may make sense for them. Now, when a person's valve is leaking, in general, as you know, we just repair it. I mean, that's the right thing to do.



Yesterday, I had a gal who actually had a big bar of calcium in her valve. We took the big bar of calcium out, reconstructed with a patch, added the patch to the back leaflet of the valve so we rebuilt the back leaflet, and then the valve worked perfectly. She's off the ventilator leaving the op-room. She's sitting up, walking around now, chatting with her family, and she's 74 years old. She's not young; she's not old.

My point is it has to be very specific to the patient. When it comes to rheumatic disease, as rheumatic disease progresses, it's severe insufficiency. Those typically are very amendable to a minimally invasive mitral valve replacement. In this case, the aortic valve has already been replaced, so typically we would either approach through a small incision on the right side or if there was some reason we were going back through the middle, we have an approach that takes us through both atria to get to the mitral valve.



Age & Heart Valve Surgery

Adam Pick: Dr. Gerdisch, I think folks online may have heard you say you're going to be operating on an 89 year old patient tomorrow.

Dr. Gerdisch: Yeah, two of them tomorrow; I have two 89s.

Adam Pick: So I'm sure patients are wondering or thinking in their heads, "What's the oldest person that you've taken into surgery?"

Dr. Gerdisch: I think probably 94. I've had a couple of 94 year old folks. One of them that jumps to mind is the 94 year old guy that we did a minimally invasive mitral valve repair on and he was back riding his bike the next week. People are – everybody's a little bit different. We all have our stories. I recently did a triple valve on an 89 year old woman. She's doing okay. It's going to take a little while to bounce back. She's going to be all right. She's up walking around. She feels okay. It's going to be a little bit of an up and down for her.

We just talked about all of those things and the potential for the ups and downs after surgery, and we let people decide if they're in for it. There are different kinds of 89 year olds. The one tomorrow, for example, one is a really robust guy, needs a double valve. The other one is a little bit more frail gal that has this horribly calcified mitral valve. We don't want to just tell her she can't have surgery. We explained to her what the situation is and then we take care of her.

Yeah, we have obviously the full spectrum, and sometimes I find myself operating on 20 year olds and sometimes I find myself on the nonagenarians, but it's all a matter of what stage of their pathology they're in, what their frame of mind is, and what level of life they're trying to live.



Eligibility for Minimally-Invasive Heart Valve Surgery

Adam Pick: Let's go to a live question that came in from John, who asks right on this topic, Dr. Gerdisch, "How is it determined if one is eligible for a minimally invasive surgery as opposed to a full sternotomy?"

Dr. Gerdisch: Right, so it really depends on multiple factors; it depends on who the surgeon is. It depends on the nature of the pathology. Now, these, again, can be long conversations, but let me highlight a couple things. Number one, minimally invasive surgery is great. Love to do it. I think it's super important that we recognize that whatever operation we do is an all-encompassing procedure that takes care of every bit of pathology the person has. If it means that I have to switch to a sternotomy in order to do three valves and a maze on somebody instead of just doing their mitral, then I switch to the sternotomy. Sometimes we'll do two valves through a small incision and that's fine when it's safe and appropriate.

The most important thing is getting the right operation and the right size valve and the right procedure done for the patient. Now, this is also one of the reasons I wanted to take some of that anxiety away from people. So this week, I did a few minimally invasive surgeries through the side, and then I did a few through the sternum. The incisions are getting close to the same size, and the recovery is the same because of the way we manage the sternum. Usually, even for a sternotomy, we can keep the incision small or do a partial sternotomy or whatever. I mean, a sternotomy is a sternotomy. You just have to be able to manage that bone well and do an orthopedic repair.

So the things that will decide are who the surgeon is, what your pathology is,



and being sure that there's an appetite to take care of everything that needs to be taken care of. Don't focus too much on the approach; focus on what the global outcome is for the operation. There are ways to make the incision smaller even for a sternotomy. We're even now working on making the scars go away. We've got some dressings that we're using that are really impressive in the way that they minimize the scar. Those are aesthetic things; I know they mean things to people, though. That's why I pursue them; I don't brush them off because they do mean things to people.

That's my answer. You'll look at the anatomy, see what the procedure's going to be. For example, that lady that I just did that I took the big calcium chunk out of, the big bar of calcium out of, we first look – I first met her and I was going to do a minimally invasive valve and then I looked at the scans and they had this big bar of calcium. If I do a minimally invasive valve, the chances of me taking that big bar of calcium out and reconstructing the entire valve with a patch and extending the leaflets is small. Through a sternotomy, it's very high. That's why we shifted, and she didn't mind. She had the same recovery as the person earlier that day that had a minimally invasive thoracotomy approach.



Rigid Sternal Fixation Utility

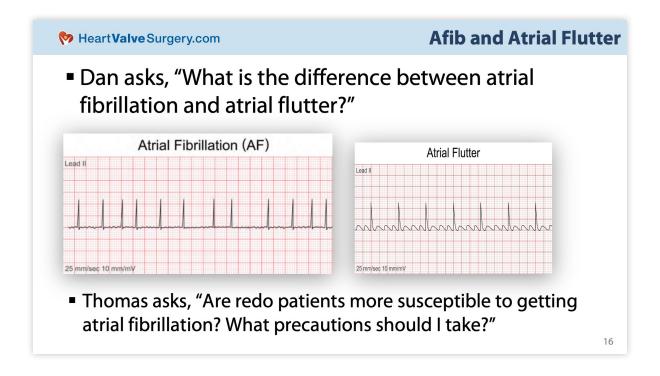
Adam Pick: For the people who do have to have the sternotomy, Dr. Gerdisch, what percent of your patients are getting the rigid sternal fixation versus a wire?

Dr. Gerdisch: Yeah, it's a great question, Adam, and it's starting to finally catch on a little bit. It's been 100% of our patients for several years. Once we studied it, again, we brought the devices in; we did the studies; we published those studies; we showed the hospital what the implications were. We have this wonderful administration that really is interested in outcomes, really interested in what we can do to expedite the recovery, so there was buy-in from the hospital.

So, for seven years, every human being that I or my partners have operated on has had rigid fixation. We're even advancing that game now; I've got some new devices in tandem with it. Yeah, I think that that's an important question if what does that mean to the person's recovery and how important is it to the patients? To some people, it may not be that important. To a lot of our patients, it's very important.



Atrial Fibrillation & Atrial Flutter



Adam Pick: Moving over to that other specialty to yours, I've learned an incredible amount from you, Dr. Gerdisch, about atrial fibrillation. We've got two questions here. First one is from Dan. "What is the difference between atrial fibrillation and atrial flutter?"

Dr. Gerdisch: Great question, Dan. As a student of the most prolific and greatest authority on surgical arrhythmia management, Jim Cox, I do have answers for this. Atrial flutter is essentially a circuit, an electrical circuit in the upper chamber of your heart. It can be either one, that is just running. So you've got this circuit in the tissue that's running around, and around, and around. Every time it comes around, it sends a signal to the AV node, which is the gatekeeper between the upper chamber and the lower chamber of the heart. That gatekeeper will decide how many of those signals are supposed to go through. That's why when you look at that atrial flutter tracing, you see all those bumps? Those are what we call p-waves or depolarizations of the atrium, the upper chamber of the heart. So that is an electrical event in the upper chamber of the heart.

Now, you can see they don't all get through. If they all got through, this patient's heart rate would be like that. You have this gatekeeper, most of us do, a functioning AV node that only lets certain ones get through. So you have this circuit. Now, why does a person have atrial flutter? They have to have substrate for it. The substrate is a pathway that's long enough and that recovers at the right pace. As the signal comes around, the heart muscle is recovering in that area and also creating slow conduction so that it can come around and not hit an area that hasn't recovered because if it hits an area that hasn't recovered, it extinguishes. You have to have the right substrate, so it has to be the slow action and the slow movement of the signal. Usually that means size, too; the bigger the atrium, the easier it is to have this larger pathway that allows this to happen. That's that one pathway.



Now, if I add three or four more of those, it looks like atrial fibrillation. So atrial fibrillation is kind of the big brother. It is the more disorganized. It is the more prevalent tissue activation. There's so many different ways that it's been studied that people are getting confused about it. Initially, it just meant that you had a lot of these large rotors, but now they're finding that there are smaller spaces that can generate the activity as well.

What we do know is that with isolation of the tissue for atrial fibrillation and with breaking those rotors for atrial flutter, we can get rid of the arrythmia, and that goes back to Dr. Jim Cox, whom I mentioned earlier who invented the Cox Maze operation, which stands still for the definitive operation for atrial fibrillation.

Atrial flutter's a little bit easier to address, especially if it's on the right side. The right side, the electrophysiologist can almost invariably treat it. On the left side, it's harder for the electrophysiologist to treat it percutaneously. That's the fundamentals of it.



AFib for Reoperative Patients

Adam Pick: To Thomas' question. "Are redo patients more susceptible to getting a-fib? What precautions should I take?"

Dr. Gerdisch: It's actually really insightful question because if you've already had heart disease and you're coming up on needing a reoperation, chances are you've got something going on where this valve that you have now needs to be redone, re-repaired, re-replaced, whatever. So in that time span, there's a good change that your atrium is developing more pathology. Now, there are some people that you cannot give atrial fibrillation to. They just won't get it, but most of us are vulnerable if our substrate changes. So as the atrium enlarges, as it gets more fibrotic, which happens as people have heart valve disease and progress in that pathology to the point of needing a reoperation. They are going to be more vulnerable.

The other thing is there's probably a little more inflammation in the chest after a redo, and inflammation is one of the drivers for a-fib. As far as precautions go, your physician may or may not want to use a preemptive medication. We use amiodarone for folks before surgery sometimes. That seems to quiet it down, but you can't do especially you can't do anything to address it yourself. This is just a matter of what the substrate of the heart muscle looks like and the inflammation around the time of surgery.



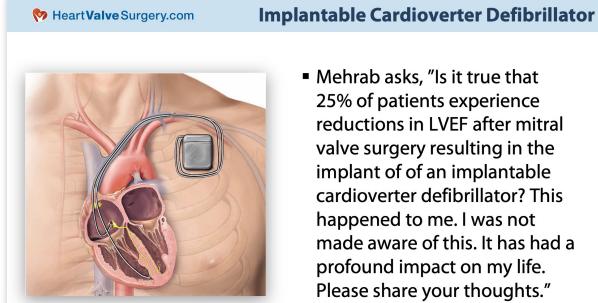
Exercise

Adam Pick: Real quick, Mark's live question is, "I'm an 87 year old male. I've got a-fib for ten years, leaking aortic valve, slight mitral prolapse, shortness of breath. Can I still exercise?"

Dr. Gerdisch: The answer is generally yes. The severity of the leak of the aortic valve would be important because if you stress that too much, you could run into trouble. I would always advise people to exercise but also within the construct of understanding how severe their valve pathology is. That would be something you'd have to ask the cardiologist or have somebody take a look at the echocardiogram. It's probably not leaking severely if they're being managed medically, in which case I would say yes, you may still exercise.



Implantable Cardioverter Defibrillators



Mehrab asks, "Is it true that 25% of patients experience reductions in LVEF after mitral valve surgery resulting in the implant of of an implantable cardioverter defibrillator? This happened to me. I was not made aware of this. It has had a profound impact on my life. Please share your thoughts."

Adam Pick: Great. Here's one about an implantable ICD. Mehrab asks, "Is it true that 25% of patients experience reductions in left ventricular ejection fraction after mitral valve surgery resulting in the implant of an CVD? This happened to me. I was not made aware of this. It has had a profound impact on my life. Please share your thoughts."

Dr. Gerdisch: So it depends on which type of mitral valve surgery it is, of course, and it depends on why the pacemaker defibrillator was required. So implantable cardio defibrillator, so I assume that this is also a pacemaker. Actually, it's interesting. There was a recent study that was just published looking at mitral valve replacement or mitral valve surgery and the requirement for pacemakers; it was just published. They could not discern a survival disadvantage to the patients who required a pacemaker after mitral valve surgery.



This was really interesting to me because we do see a difference in survival overall for people who had aortic valve replacement and require a pacemaker, so why does it happen? Probably because with an aortic valve replacement, the most common issue is that patients get a – they can develop left bundle branch syndrome or they develop a pacemaker syndrome after having a pacemaker put in, so they can have some disadvantage.

Mitral valve, for some reason in this study, which had thousands of patients, they didn't see that difference. I would add that after mitral valve repair, pacemakers are extremely rare. Mitral valve replacement, 3% to 4% of those people go on to require a pacemaker. The pacemaker, though, is typically not because of a reduction of left ventricular injection fraction; it's because there is a block in the electrical conduction pathways, so you can see these are different animals.

Now, when people have a decline in their left ventricular injection fraction after mitral valve surgery, usually it's in the subset who had a badly leaking valve; they had it for a long time. The left ventricle became overloaded, suffered fibrotic changes. Meanwhile, the heart has been working against this path of least resistance where it's pumping blood backward through the mitral valve. When you do the operation, you take that away and a ventricle that may have been kind of in the normalish range before, like 50% ejection fraction, all of a sudden it drops down to 25% because it's doing what it can do. That may well have been what would happen.



As far as 25% of patients, that's kind of a big number, to be honest. I think it's probably not quite that high. The reason to have the defibrillator and to have the pacer, I'm not sure. There are particular types of pacers that improve the squeeze of the heart if the patient has a particular type of conduction abnormality; those are called biventricular pacers. Those devices can really help the heart recover.

I don't know that it's actually 25%; it's certainly not 25% of them go on to need a defibrillator. That's definitely not true. There is a subset of patients who, after mitral valve surgery, especially if they've had a bad leaking valve, end up with requiring that because their ventricle shows its true colors. That's possible.

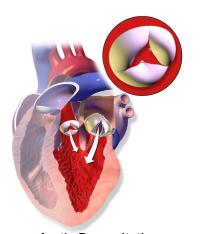


Watchful Waiting: Aortic Regurgitation

Heart Valve Surgery.com

Aortic Regurgitation & More

Susanne asks, "I'm a 63-year-old female with mild asthma. Diagnosed with moderate aortic regurgitation in 2021. Now, I have mitral stenosis and mild tricuspid regurg. So far, EF is 60% and right/ left atria and ventricles are normal size. I get out of breath and have occasional palpitations. Does the moderate aortic regurgitation have anything to do with affecting the other valves? Am I good at just getting an annual echo at this point? Should I be more vigilant?"



Aortic Regurgitation

19

Adam Pick: Let's talk about something I don't think we've talked about yet, which is aortic regurgitation. Susanne asks, "I'm 63 years with mild asthma, diagnosed with moderate aortic regurgitation," a few years ago. "Now I have mitral stenosis and tricuspid regurg. My ejection fraction is 60%, right and left atria; ventricles are normal size. I get out of breath and have occasional palpitations. Does moderate aortic regurgitatoin," we talked earlier about moderate stenosis but, "Does moderate aortic regurgitatoin have anything to with affecting the other valves? Am I good at just getting an annual echo at this point or should I be more vigilant?"



Dr. Gerdisch: Susanne, it's a great question because you're trying to be insightful about your own process and you have some symptoms. Unfortunately, your case is a little bit interesting because you have aortic insufficiency but you have mitral stenosis. What would really result in that in a 63 year old person? So the first thing I would think of, quite honestly, is rheumatic disease. Did you have rheumatic fever as a child, maybe even not know it? Because in rheumatic disease, the aortic valve may not get stenotic and it might leak because the leaflets curl up a little bit and they don't close all the way. Then you find in looking at the mitral valve, as the leaflets thicken and lose mobility, you start to see mitral stenosis. You don't say how much mitral stenosis you have here.

On the other hand, there could be different disorders, so you've got an aortic valve that leaks because the annulus has stretched out where the leaflets attach, but then you also have calcium developing in the mitral valve creating stenosis. In your case, with the fact that you have some symptoms, the two things I would want to do are I'd want to monitor for those palpitations. Any time you have them, if there's a way for you to find out if you're having atrial fibrillation, I think that's important. People can have a few palpitations and find out later that they're having atrial fibrillation. In your case, I'd probably be doing echoes every six months. I'm not going to speak out of turn for your physician, but once I see moderate, I typically want to see things every six months. An echo is an inexpensive, easy way to know if anything has changed, and you're trying to stay right on top of this.



So the mild tricuspid regurgitation I wouldn't worry about. The mitral stenosis, it depends how severe it is; my suspicion is it's mild. Then the aortic regurgitation, if it's definitely moderate, truly moderate, then I would follow that a little bit more closely. As long as your ventricles and atrial look normal in size and function and strain, I would add strain, then I would say you can kind of chill and enjoy your life. You might deal with some odd symptoms, but if any of those things change, any of those parameters change, then you have to think about doing something.



Lifetime Management of Aortic Valve Disease



Adam Pick: Dr. Gerdisch, here's an interesting question. You mentioned earlier, and I think it's so important for the folks on the line to focus on this, this idea of lifetime management of your valve disease.

Here's one from Keli. It says, "In 2009, I had an aortic valve repair for my bicuspid aortic valve. Recently, a big increase in stenosis. At 56, what are my options? Am I too young for TAVR? Am I too old for the Ross procedure? Are there minimally invasive opportunities? Other than my heart, I live a healthy, clean lifestyle, yoga, and walk daily."

Dr. Gerdisch: Wow, great case. So yeah, Keli, this is something that can happen. We always hope the repaired bicuspid valve is just going to last forever, but we don't know, and we know it's abnormal tissue when we repair it. So you got a pretty good run out of this valve. Now you're only 56. Yes, you are too young for TAVR: I'm just going to tell you that for sure. You are not too old for a Ross, so people like you who are particularly healthy, they do get done in folks over 50. If I'm being absolutely honest, because I reviewed those papers; the results were a little bit mixed over 50. You sound like a particularly healthy person, so it might be a good option for you. It might make sense for you just recognizing that over 50, there's a little bit more of a chance the pulmonic valve might not be usable. You also have to deal with the potential for reoperation no matter what.

Now the next question is, what do you do if you're not going to do that? So you're 56; you're healthy. Personally, I would probably think about an On-X mechanical valve. Your probably are averse to anti-coagulation. You don't want to be on coumadin; nobody does. In my mind at that age, and I'm a little bit older than you and I personally would lean toward an On-X valve because you can have a device that will never change for you that you do have to manage with a blood thinner, but at least you're one and done.

If you have a surgically implanted tissue valve, that's still acceptable at 56. The data says your survival is not quite as good over the long run; we had a recent paper last year. Dr. Bowdish showed us that people under 65 probably still benefit from having a mechanical valve, but it's not unacceptable. You'd want to make sure that you have a good sized tissue valve that's going to last you a long time and then potentially, maybe, if that's what you need later, a transcatheter valve in there.



At 56, if you get a tissue valve now, chances are you're going to get another operation because you're really healthy and you're going to live a long time, especially with bicuspid. People with bicuspid valves tend to live a long time because they tend to be healthier. As a subgroup, we have to think of them as living into their 80s and 90s. I would say feel free to get evaluated for Ross; it's possible. Like I said, the data is mixed over 50. Personally, I would think in terms of an On-Xx mechanical valve because of the survival advantage. If you can't accept that, then get a big tissue valve. Minimally invasive? Depends a little on the overall anatomy of things, but typically if you've already had one sternotomy for an aortic valve, typically we would use that sternotomy again but then with the advantage of putting the bone back together in an orthopedic fashion so that you can just get back in action right away.



Thanks Dr. Gerdisch and Our Patient Community

Adam Pick: Out of respect for everybody's time, we're going to end the webinar, but please don't hang up just yet. I want to go ahead and thank Dr. Gerdisch. As always, I think we could've gone on for another couple hours.

Dr. Gerdisch: I've got time.

Adam Pick: We only have 60-some more questions to go. So I want to thank you and your whole team there for taking such great care of our patients over the years and to all the folks on the line, I just want to express my gratitude and appreciation for your commitment to your own cardiac care. We are here together as a community and for me, there's no better time for doing these webinars and getting together and sharing these experiences with world-renowned physicians to coach us along the process.

So I'm going to go ahead and end the webinar and if you could, just complete the survey that's coming up, we'd really appreciate it. Thanks so much, Dr. Gerdisch. Thanks, everybody.

Dr. Gerdisch: Bye, everyone. Thanks!



Patient Resources

Since 2006, <u>HeartValveSurgery.com</u> has developed several resources to help you better understand your diagnosis, your treatment options and your recovery.

Listed below, please find resources created exclusively for patients and caregivers. We hope they educate and empower you.

- Adam's Free Patient eBooks Download 10+ free eBooks about heart valve disease and treatment options for aortic, mitral, pulmonary and tricuspid valves.
- <u>Heart Valve Learning Center</u> Visit the Heart Valve Learning Center to access over 1,000 pages of educational information about valvular disorders.
- <u>Patient Community</u> Meet people just like you in our patient community. There's nothing better than connecting and learning from patients who are sharing their stories in our community.
- <u>Surgeon Finder</u> Find and research patient-recommended heart surgeons that specialize in heart valve repair and heart valve replacement procedures.
- <u>Heart Hospitals</u> Learn about medical centers that have dedicated teams and resources that specialize in heart valve therapy.
- Adam's Heart Valve Blog Get the latest medical news and patient updates from our award-winning blog.
- <u>Educational Videos</u> Watch over 100 educational videos filmed by the Heart-ValveSurgery.com film crew about heart valve surgery.