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Introduction



Adam Pick: Hi, everybody. My name is <u>Adam Pick</u>, and I'd like to welcome you to the webinar titled Advances in Aortic Valve & Aneurysm Surgery. If I have yet to meet you, I'm the aortic valve patient who started <u>HeartValveSurgery</u>. <u>com</u> 15 years ago in 2006. The mission of our website is very simple. We want to educate adn empower patients, their family members, and friends about valvular conditions and treatment options. This webinar, which has had over 980 registrations from patients - in countries all over the world - was designed to support that mission.

Throughout the webinar, you're going to be in what's known as "listen only" mode, but I would encourage you to submit your questions in the control panel that's on the bottom part of your screen. I'll explain why in a minute.



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As for the agenda for today, I'm going to start with an introduction of our speakers. We're going to talk about aortic valves and aneurysms. Then, we'll have a very in-depth conversation about the treatment of those cardiac diseases. We will a do real-time Q&A based upon questions submitted by the patients in our community. Lastly, I'm going to ask you to complete a very quick five-question survey.

When it comes to the featured speakers of today, I've got to tell you I'm not only honored but I'm completely humbled that they are taking time away from their incredible practices to spend it with us and be with our community on such an important topic.



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Dr. Joseph Bavaria is the Vice Chief of Cardiovascular Surgery at Penn Medicine Heart and Vascular Center in Philadelphia, Pennsylvania. During his extraordinary career, Dr. Bavaria hasn't performed two, five, six, but 9,000 cardiac procedures of which more than 6,000 involve some form of heart valve repair or replacement.

When it comes to his specialties, Dr. Bavaria is not just nationally known. He is world-renowned for his commitment and dedication to aortic valve disease and aneurysms. He is a co-director of the Aorta Center at Penn Medicine, and he is so revered by his peers and his colleagues, Dr. Bavaria is a past president of the Society of Thoracic Surgeons. It is great to have him on the call. I've got to tell everybody out there, the first time I heard about Dr. Bavaria was from who? His patients. As I started HeartValveSurgery.com, I started hearing from all of his patients saying, "I'm getting the best results and Dr. Bavaria is an incredibly nice person. So Dr. Bavaria, thanks so much for being with us today.

Dr. Bavaria: Thanks, Adam.



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Adam Pick: Dr. Nimesh Desai is the Co-director of the Aorta Center, and he is a director of the Thoracic Aortic Surgery Research Program at Penn Medicine with Dr. Bavaria in Philadelphia, Pennsylvania. Dr. Desai is an aortic valve and aneurysm expert, and he is also very interested in utilizing minimally invasive techniques to treat these disorders, one of which being transcatheter aortic valve replacement. Throughout his career, he's performed over 4,000 cardiac procedures, with more than 2,500 involving heart valve therapy. I've got to thank Dr. Desai who's helped me and our community just most recently learn all about reoperative techniques in a video we filmed together. Dr. Desai, thanks so much for being with us today.

Dr. Desai: Thank you, Adam. Thanks for putting this together.

Adam Pick: I could talk on-and-on about all of the accomplishments, the accolades, the achievements of Dr. Bavaria and Dr. Desai. It's clear we have a "Dynamic Duo" with us today. Instead of just going through all the great things I could say about these physicians, I would like to show you this.





These are smiling pictures of the success stories from Penn Medicine, whether it's John, Steven, or Mark, and John. By the way, John is a retired NFL football player for the Philadelphia Eagles. In addition to all the smiling faces you see here, there's the names, and these are all patients from the HeartValveSurgery. com community that have gone to Penn Medicine and had successful therapies with Dr. Bavaria, Dr. Desai and the Penn Medicine team. Again, I'm incredibly honored to have both Dr. Bavaria and Dr. Desai here.

To start this webinar, we're going to turn it over to Dr. Desai to learn all about aortic valve disease and aneurysms



Aorta Anatomy



Dr. Nimesh Desai: Thank you, Adam. That was a fantastic introduction, and it's such a privilege to talk to so many people from around the world today about something that – it almost sounds like a cliché – is something very near and dear to both myself and to Dr. Bavaria. It's what we do every day. It's what we think about every day. It's what we dream about at night probably as well.

Let's start with some basic principles. The audience here from the questions is super, super knowledgeable about the aorta and the aortic valve. I don't want to make this too simplistic.



For those who need an introduction, the aorta is the big tube, the pipe that carries blood from the heart, squeezes it out, oxygenated blood to the whole body to give it nutrition. The entrance to the aorta is actually where the aorta meets the heart. That's called the aortic valve. The aortic valve is a one-way door that opens when the heart squeezes, lets the blood out of the heart, and when the heart relaxes, it closes, so the blood keeps flowing in a forward direction.

The area of the aorta we're going to talk about today is that part of the aorta really close to the heart where that yellow arrow is there in the figure with the person there.

That is the ascending aorta and also the root, which is the part of the aorta that actually attaches into the heart and has the aortic valve in it.



Embryological Development of the Aortic Valve & Root



Dr. Nimesh Desai: The reason we're discussing this together, the aorta and the valve, is because the aortic valve is the aorta so when we're developing embryologically, in utero.

The heart starts as this tube and then eventually turns and becomes this amazing four-chambered structure with four heart valves in it. If you look at the panel on your right there, the yellow, you'll see the aortic valve actually grows out of the actual wall of the aorta. That's why when you have a disease in one of these cardiac structures, you often have diseases in the other. So, the concept of the aortic valve and aortic aneurysm are very tied together.



What Is An Aneurysm?



Dr. Nimesh Desai: The next question is, "What is an aneurysm?"

An aneurysm is when your aorta is enlarged or it's bulging out. Some people will call it a bubble on the aorta, which isn't really true, but it's a bulge or an enlargement of it, and it happens because the wall of the aorta has weakened somehow. If the whole wall has weakened, you have a true aneurysm. If there's a little focal area or small area, you might have an ulceration or a pseudoaneurysm, which is just a fancy way of saying an ulcer or a small hole. If the wall splits and you actually have blood flowing in two channels which is called an aortic dissection. Obviously, that's a really dangerous thing to have and can be very life threatening.



Importance of Aorta Size



Dr. Nimesh Desai: What's a normal aorta? A normal aorta depends on a few different things, but for the average person, it's usually less than 3.5cm. Anything up to 4 cm is usually not too concerning. But once the aorta gets larger, it has a risk of actually developing an aortic complication. What that means is something bad happens to the integrity, or wall of the aorta, and it tears. It can either tear and develop into something called a dissection, or it can tear and actually rupture, which is where you just bleed out, which is really bad. So these are things we want to avoid, and this is why we care so much about monitoring people's aortas and identifying aneurysms and repairing them before it's too late.



To put it in context, typically, when the aorta starts to develop complications is a little bit more than 5cm. Somewhere between 5cm and 5.5cm is where we start to see a pretty big uptick in the risk of something bad happening to your aorta.

That's why we usually intervene somewhere in that range.

What does 5.5cm look like? A big Coke can is 5.8cm, so it's a little bit bigger than that. Think about how big that is. It's actually huge, and the regular aorta, a normal-sized aorta, is like the size of an inside of a toilet paper roll. That's a huge difference.



Aortic Dissections: What Should You Know?



Dr. Nimesh Desai: When something bad happens to the ascending aorta, it's usually an aortic dissection. That is when the inner lining rips and then blood goes out of the main channel of the aorta into something called a false channel or a false lumen.

So you don't rupture and just bleed out right away – which is often what happens with abdominal aneurysms when they rupture. These ascending aneurysms typically will dissect and not rupture right away, although they will eventually rupture if this is not treated.



One of the consequences of this kind of tearing is that it can actually knock off the blood vessels that are connected to the aorta, like the blood vessels to the brain, like the carotid artery, or blood vessels to your intestines or your legs. So, you can develop loss of blood flow because the tearing of the artery actually cuts the blood supply off.

Usually, we think when someone has an aortic dissection that we call acute or immediate that there's almost a 2% risk of dying per hour if it's not fixed. We always want to try and fix aneurysms before they get to this point.



Ascending Aortic Aneurysm Causes



Dr. Nimesh Desai: Why do aneurysms happen? That's a pretty complicated question. A lot of it has to do with genetics. On the right panel there, there's a crazy slide with a bunch of different genes right there and compounds. These are all the different things that keep the wall of your aorta healthy. That's probably not even a tenth of the ones that are actually involved.

It's really complicated, but there are some clear genetic syndromes – so a change in a gene that actually causes the wall of the aorta to not be as strong because some of the components are not created properly or missing completely. Marfan syndrome, Loeys-Deitz syndrome, Turners are all syndromes that are highly associated with aortic aneurysm.



The most common reasons why we see aneurysms in our practice are bicuspid valve related aneurysms. So, bicuspid valves have aneurysms associated with them. There's also something called genetic non syndromic aneursyms. They're aneurysms that run in the family. They're related to some kind of complex genetics, not the usual stuff, but something more complicated that's harder to understand, but the patient doesn't have a syndrome associated with it.



Genetic Syndromes & Aneurysms



Dr. Nimesh Desai: Genetic syndromes like Marfan's or Loeys-Deitz have a variety of different changes associated with them. It'snot just that the aorta is enlarged or they have an aneurysm, but there might be other skeletal features, bony issues, tendon issues, ocular issues, clef palate, all kinds of different things that are associated.

So those are syndromes, and part of those syndromes is the aortic issue. The syndromic genetic aortic conditions generally appear very young and often even in childhood. In particular something like Loeys-Deitz, we may see aortic valve and root aneurysms happening even in the pre-teen years.



Bicuspid Aortic Valves Explained



Dr. Nimesh Desai: The most common reason that we do see aneurysms in our practice here at Penn is actually related to bicuspid aortic valves, or we'll call it BAVs. BAVs are really common, unlike things like Marfan syndrome or Loeys-Deitz that are really rare. BAVs are actually pretty common, 1 or 2% of the overall population. Much more common in males, so there is some genetic component to it. Interestingly, if you have a bicuspid aortic valve, the prevalence in your first-degree relatives is almost 9%, so it's four or five times higher than in the general population. There is clearly some genetic element to bicuspid aortic valves, although it's not really well understood yet - even with best science.

What is a bicuspid aortic valve? It's something that you're born with. As you see in the panel there on the right, instead of having a valve that has three components that open and close, it only has two components that open and close. It can follow different patterns. The one I'm showing there is the most common one, which is two of the leaflets are fused together, and one of them is a normal leaflet.



Bicuspid Valves & Aneurysms



Dr. Nimesh Desai: Bicuspid valves are very associated with aortic aneurysms. About 20 to 30% of people will develop an aortic aneurysm 10 to 20 years after the diagnosis of bicuspid aortic valve.

Eighty percent (80%) of bicuspid aortic valve patients will have an aorta greater than 4cm over their lifetime. So, it is common for people with bicuspid valves to have large aortas. There's an 80 times higher rate of aneurysm formation than the general population. and at least in our practice, 50% of all root operations in the patients over 50 years old are bicuspid related.



Flow Mediated Aneurysm Formation



Dr. Nimesh Desai: The reason why aneurysms form in bicuspid patients is complicated. Part of it we think is related to the genetics of why it happens in the first place. The other part has to do with blood flow. The flow going through a bicuspid valve is very different than through a normal three-leaflet valve, and it actually can put a lot of stress on the aorta. The jet of the blood can actually be pounding on one part of the aorta the patient's whole lifetime and actually cause it to stretch and develop an aneurysm. These are different patterns of aneurysms that can form.

Adam Pick: For a patient who's never heard that term "jet" before, can you explain what that means?



Dr. Desai: Yes, absolutely. You see those arrows coming out of the valve? That's a pictorial representation of the swirl of blood as it comes out of our heart. We call that ejection, or the push of blood out of the heart, a jet. You can see here the jets are going in all kinds of different directions, and they're pounding in some situations right on the wall of the aorta in specific orientations. We think causes weakness.

Comparatively, in a three-leaflet valve, that jet goes straight up to the brain and doesn't hit the walls of the aorta.



Patterns of Bicuspid Valve Aneurysm



Dr. Nimesh Desai: You can develop different types of aneurysms in bicuspid valves, and that explains some of the different operations that you may have had or need in the future for an aneurysm with a bicuspid valve.

Sometimes they're just above what we call the "root", where the valve is. Sometimes they involve the entire root and ascending aorta. So, the root again is that bulbous part down by the bottom here the valve is. Then, sometimes the entire thing can be aneurysmal, and so those are all different patterns, and these are reasons why we do different operations for different pathologies.





What I want to show is in this figure... You can see there's different types of valve openings. There's the kind where it opens almost like a fish mouth, and you have two equal leaflets. There's the kind where there's – two leaflets are fused together. Then there's the kind where actually there really isn't leaflets at all. It's like one huge leaflet that's fused together and there's a slit in it. This is the one that typically we see in childhood. If someone has a valvular obstruction as a kid and needs a procedure as a child to open it up, that's frequently what we see. Most people who have stenosis or narrowing of their aortic valve in the younger age groups, 20s, 30s, is often this third type, which is pretty rare overall

Generally speaking, the second type is 80% of people with bicuspid valves.



Natural History of Bicuspid Valves



Dr. Nimesh Desai: What happens to people with bicuspid valves? If you didn't know you had a bicuspid valve and just went and someone heard a murmur or they did an echo on you for some reason and they saw, oh you have a bicuspid valve – didn't have any symptoms, wasn't bothering you at all, this is what your natural history is.

They actually did a screening study to look at – just did echoes on an entire county of people in Olmsted County, which is near the Mayo Clinic. What they found is that if they diagnosed an asymptomatic bicuspid valve on that echo – just didn't know about it before and they diagnosed it then, that the overall survival actually is still very good. Even if you have a bicuspid valve, for the next 20 years at least, the chances of you being alive versus someone who didn't have a bicuspid valve being alive was the same, 90%.





A third of patients will develop symptoms over the next 20 years.

In the graph on the right panel there, that's a graph showing what happens if your – when they did that echo, even if you had no symptoms with your bicuspid valve, they saw the valve wasn't normal. It's bicuspid, but it wasn't working normally. There's a 75% chance that, within the next 10 years or so, you're going to have to have surgery on your valve. If the valve was working completely normal, the risk was only about 20%, less than 20%, in the next 20 years.

What your valve looks like at the time of diagnosis has a lot to do with what happens to you in the future.



Non-Syndromic Genetic Cases



Dr. Nimesh Desai: The non-syndromic genetic cases, so people don't have other abnormalities but just have the aneurysm, is an important group. We don't understand a lot about them. We don't know what the genes are, but there are people who have a family history of aneurysms, and they have an aneurysm.

Those people have a much poorer prognosis than if you didn't have a family history. So, three times higher yearly risk of having a Type A Dissection. It typically happens eight years earlier than someone with the same sized aorta but no family history. This is an important thing to watch out for.



Tale of Two Brothers

Meart Valve Surgery.com Non-Syndromic Familial Aortic Disease

A Tale of 2 Brothers...

- 57-year-old male presented with Acute Type A Dissection with loss of blood flow to the leg
- Maximum aortic diameter<5cm at time of aortic dissection, Aortic Root not aneurysmal
- Otherwise healthy
- No family history
- No known Aneurysm (never screened)
- Had successful repair



Dr. Nimesh Desai: This is what we call a "Tale of Two Brothers", two patients that Dr. Bavaria and I took care of. One was a gentlemen presented – he was 57 years old. He had an acute Type A Dissection. So that aortic dissection, had emergency surgery. He actually lost blood flow to his leg at the time, had an emergency surgery. Actually, the aorta wasn't aneurysmal. He had no family history of it, really walked into the hospital with no problems.

Dr. Bavaria operated on him and saved his life. He had a very good result over the long term.



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Fast-forward this nine years. This is a patient that I took care of but also a 57-year-old male presented with an acute Type A Dissection. Lost blood flow – had a loss of blood flow to the leg, so same presentation. The aorta wasn't that big. It wasn't aneurysmal at the time, otherwise healthy. He had a successful repair. A month later, I was talking to him in the clinic. He mentioned his brother had emergency heart surgery years ago for something similar.





Dr. Nimesh Desai: It turns out that these two brothers had almost an identical presentation, and an identical age with an acute aortic dissection. It just tells us that, number one, there's so much about this disease that we don't understand or know, but two, what can we do to really be proactive about preventing these kinds of things from happening, and understanding the genetics, looking at imaging and intense medical therapy.

When should we operate? If we've known about it, when could we have operated to try and prevent something like that? How do we help families to deal with the burden of emergency surgery, life-and-death experiences, and then knowing that children or other members of the family may be affected, as well? These are all things we think about a lot as we consider our comprehensive aortic program here at Penn Medicine.



Managing Aortic Families



Dr. Nimesh Desai: In the realm of genetic testing – this is a busy slide. It's a clinical decision-making slide. The key things I want to stress here are that having a family history – as I showed you, having a family history of aortic aneurysm is really serious.

We do recommend that if anyone has syndromic features or early age of onset, or has an aortic dissection, that genetic testing really should be done on almost everybody. Then also, if there is a family history of thoracic aortic aneurysm, that all first-degree relatives of that person should be screened - either with an echo or a CAT scan. I think that's emerging, and that's how we want to avoid some of the problems that we see with multiple family members having aortic dissections because we just didn't know about them.



Aneurysm Treatments: Medical Therapy for Blood Pressure



Dr. Nimesh Desai: How do I treat aneurysms? Well, one of the things we would want to do is try and prevent them from growing or tearing, right? Blood pressure medicines, I'm sure your cardiologists have all talked to you about being on blood pressure medicines, beta-blockers like atenolol, metoprolol, losartan, which is an angiotensin receptor blocker, are all very good at preventing growth of the aorta in patients with syndromic aortic conditions like Marfan's. We don't know that they're as good for people with bicuspid or other aneurysms, but we still recommend being on one of these agents for blood pressure control. We ask people to avoid heavy weightlifting, not more than a third or half of their body weight, and often even less if the aorta is larger; 50 pounds is often a restriction we'll put not to put too much strain on their aorta. Avoid high G-force or sudden decelerations like fighter jets, roller coasters, or high-impact sports, as well.



Alert! Fluoroquinalones and Aortic Rupture



Dr. Nimesh Desai: Fluoroquinolones, so antibiotics like ciprofloxacin, Levaquin, which are really commonly used for bronchitis or pulmonary conditions and sometimes UTIs, or urinary tract infections, have been shown to double your risk of having an aortic catastrophe. Patients with aneurysms should never take these medicines unless there are no alternatives, and really advocate on your own behalf for that because this is something I feel like the medical community really is not aware of enough.





Dr. Nimesh Desai: When do we intervene? Well, it really depends on the person and what they have. Genetic syndrome, we're looking at operating at smaller numbers, like 4.5cm to 5cm. Bicuspid with some valve disfunction, somewhere between 4.5cm and 5cm. Bicuspids with normal function, between 5cm and 5.5cm. Non-syndromic familial between 5cm and 5.5cm. If we know something about their genetics, that complex panel we see on the right side, then we might follow those guidelines in terms of when we do it. If it's growing a lot, we'll operate earlier. If we're in there doing an aortic valve replacement because the aortic valve is not functioning, then we'll usually do it at 4.5cm.



Aortic Size Index

Aorti (Aortic diam	Size I I eter (cm) /	nd HE	le: IGI	Х HT	(m	1)						
A larger person has a larger Aorta!							Aertic	Size (cr	n)			
and the second se			3.5	4.0	45	5.0	5.5	6.0	65	7.0	75	8.0
<u>Q</u>	Hei (inches)	ght (m)	010				eie	010	010			010
	55	1.40	2.50	2.86	3.21	3.57	3.93	4.29	4.64	5.00	5.36	5.71
	57	1.45	2.41	2.76	3.10	3.45	3.79	4.14	4.48	4.83	5.17	
	61	1.55	2.33	2.58	2.90	3.23	3.55	3.87	4.19	4.52	4.84	
	63	1.60	2.19	2.50	2.81	3.13	3.44	3.75	4.06	4.38	4.69	5.00
	65	1.65	2.12	2.42	2.73	3.03	3.33	3.64	3.94	4.24	4.55	4.85
	67	1.70	2.06	2.35	2.65	2.94	3.24	3.53	3.82	4.12	4.41	4.71
	69	1.75	2.00	2.29	2.57	2.86	3.14	3.43	3.71	4.00	4.29	4.57
	71	1.80	1.94	2.22	2.50	2.78	3.06	3.33	3.61	3.89	4.17	4,44
	73	1.85	1.89	2.16	2.43	2.70	2.97	3.24	3.51	3.78	4.05	4.32
	73	1.90	1.84	2.11	2.37	2.63	2.89	3.16	3.42	3.68	3.95	4.21
	77	1.95	1.79	2.05	2.31	2.56	2.82	3.08	3.35	3.59	3.85	4.10
	70	2 1111									100	

Dr. Nimesh Desai: We do index to size, as well. We know that larger people do have larger aortas. This gentleman here, who I think was the tallest person that ever lived, was 8'11". I don't know how big his aorta was, but it was probably at least twice as big as mine is. What's normal for one person isn't necessarily normal for another person. We do index it to the size, as well, when we make decisions about whether or not to operate.



Treatment Options



Dr. Nimesh Desai: Then, finally, when we start talking about what we're going to do, what are the treatment options for someone who has the aneurysm with or without valvular disease, we're thinking about what's the status of the aortic valve? Is it narrowed, or is it leaking? That helps determine what we're going to do. Where is the location of the aneurysm? Is it down in the root, in the midascending, or up in the arch?

Our algorithm usually is if there's aortic stenosis involved, so the valve is narrowed. It doesn't open well. It's calcified – has chunks of calcium in it. It's not flexible and pliable and elastic anymore. Those type of valves we typically need to replace. Valves that are leaking, sometimes we replace them, but we usually try to repair them, if possible.



Aortic Valve & Root Replacement Options



Dr. Nimesh Desai: In terms of ways to replace – so again, we're looking at replacing the aorta, replacing the valve. The first panel here is a look at replacing the aorta and what's called a root replacement. You're replacing the root, the aorta, as it enters into the heart, the valve.

As well, really importantly, in that part of the heart, up where the aorta is, where the coronary arteries come off, so we have to put those back into our graft. That's called a coronary artery reimplantation. We call them buttons. Then, that white material you see there, the tube is Dacron, so it's polyester that's been treated to be safe inside a human being. It's a polyester cloth. That's what those grafts are made out of. We've been using those since the 1960s, and they're very durable.



Sometimes, we don't need to replace the roots. We actually replace just the valve because there's stenosis, and we replace the aorta. We can use a pig's root. We actually take the pig's valve and aorta and use that to replace the person's aorta. Sometimes, that's not long enough, and we'll add some Dacron to it, as well, or we can use – and we use them in infections often – is a homograft, or a human preserved aorta, so a cadaver aorta that's been frozen. We can use it to replace a living person's aorta. Those are all biologic replacements.

On the other side are mechanical replacements, so using a device that's made out of carbon and metal instead of the biologic valve. The advantage of the mechanical valve is it lasts forever. The disadvantage is that you have to be on strong blood thinners, like Coumadin, for the rest of your life. You can never miss a dose because those valves will clot otherwise. The tissue valves will eventually break down, and that can be 7, 10, or even 25 years later, depending on what's used.



Failure of Biologic Valves & Valve-In-Valve Therapies



Dr. Nimesh Desai: When the tissue valves break down, these days we have transcatheter valve technology. There's been a lot of questions about it today.

We can actually replace a failing biologic valve with a transcatheter valve. The key thing to remember there, though, is that it's not always possible to replace a failed surgical valve with a transcatheter valve because sometimes the valve is too small or there's not enough room in there to actually do it. The first operation you have needs to be a really good operation to be able to have a TAVR later.



The Ross Procedure



Dr. Nimesh Desai: Then, finally, something that I think has really come back into favor and is really becoming a big part of our practice, is doing the Ross procedure. The Ross procedure is an operation that is designed to give you a living valve replacement. That is, putting something in that's biological that can grow with you, that can get bigger with exercise, and stay healthy for the rest of your life.

What it involves is taking a different valve from your body, the pulmonic valve, which is on the right side of the heart, and putting it where your aortic valve is. You take this whole trunk out from the pulmonic side and put it on the aortic side. We may replace some of the aorta with Dacron at that time, as well.



The question is: well, what do you do on the pulmonic side? What do with that valve? Well, that's where we put a homograft in, so a cadaveric human. The advantage of this is that on the right side, it's the low-pressure side of the heart. The only thing that that right side of the heart does is take the blood, collect it, and pump it to the lungs. That valve that we put in there is not under a lot of pressure, so it can last a long, long time. On the aortic side where the valve is under a lot of pressure, it's your own valve. It's one of your own valves, so it can work just like your own aortic valve did. It can last a lifetime.

In the little graph in the corner there, on the left-hand corner, that's one of the longest series of Ross procedures out there that, even out to 25 years, there can be a 95% freedom from having any further surgery on your valve.

This is an operation that has the potential to last for a long time and in a lot of people, forever, but it's a more complicated operation. It's a much bigger surgery, and it does require certain anatomy to be just right to do it. It's something that, for younger people, we are doing more and more of.



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Here's a couple examples of that. This is a patient who had a unicuspid valve when he was young. He, amazingly, had severe aortic stenosis for probably 15 years and had compensated with it. You can actually see – this is an MRI picture where you can actually see the blood getting ejected out of the aorta and hitting the wall of the – out of the aortic valve, hitting the wall of the aorta, and actually causing it to bulge there. That's like seeing how these aneurysms form in real-time.

We did a Ross on him. He came back to me a few months later and said, "I haven't breathed this well in 15 years." It's amazing what having a wellfunctioning aortic valve can do. He has a durable solution that hopefully will last for 15, 20, 30 years.





What about bioprosthetic valves? There's a lot of patients who are young who have bioprosthetic valves. In young people, bioprosthetic valves don't last that long. If they last 8 to 10 years, we're happy. Sometimes, you get 15, but it's rare. This is a patient who had a valve done about seven or eight years ago.

The bioprosthetic valve is just not moving very well. This is an echo, and it just makes it a little bit hard to interpret, but on the next picture, you see that it's just not opening. See how it's not opening very well? It should be opening all the way to the wall of the aorta. Anyways, we took that valve out, and we did a Ross on him. We were actually able to do a really life-long operation on him at that point. He had a successful procedure and has a perfectly functioning valve now – is doing really well. Even if you've had another operation, it's still possible to have a Ross and convert everything back to a nice biologic solution for you.



Adam Pick: Dr. Desai, Dr. Bavaria and for everybody in the call, just so you know, I actually had a Ross procedure done. It's been 16 years since I've had that procedure, and I have had no complications since then. I just really want to acknowledge the Penn Medicine team for taking on this procedure. I understand how it is much more complex, but again, if you can create that long-term result for your patients, it's a big, big win. I just want to let everybody know if you have questions out there about the Ross procedure, don't hesitate to email me, and I'll get back to you as soon as possible. My email is adam@heartvalvesurgery. com. Sorry for interrupting, Dr. Desai.

Dr. Desai: That's amazing for you to share that with us and your experiences. Okay. I'm going to hand it to Dr. Bavaria now.



Important Patient Questions About Leaking Aortic Valves

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TWO IMPORTANT QUESTIONS:

Can we save/repair leaking aortic valves?

And... Why is repair so important?

Dr. Joseph Bavaria: Two things for everybody to consider, especially for leaky valves, is "Can we repair the valve?" and "Why is this so important?"

Now, we're talking about reparative surgery.



Valve-Sparing Root & the David Operation



Dr. Joseph Bavaria: In many cases, when we have leaky valves or we have aneurysms with relatively normal valves, we can actually repair or retain these valves. One of the ways we do it is called a David operation or a valve-sparing root procedure. What you can see is – what we do is we take out the aneurysm. Then, we reimplant a normal valve, whether it's a three-cusp valve or a bicuspid valve, into this new root. This root is designed specifically for you. In other words, it's custom-made in three dimensions for each individual patient. Then, we either keep the valve and don't have to do anything to it. Or, for example, in a bicuspid valve, we'll repair the bicuspid valve at the same time. This is a valve-sparing repair and is really a very, very good thing. This is, probably for leaky valves, the main issue.



Young Patients with Marfan Root Aneurysm



Dr. Joseph Bavaria: Here's an example. That's a Marfan's patient on the left, with a gigantic aneurysm; you can see it. Then, on the right side, you can see the new root, which is the white stuff. We've reimplanted this beautiful valve inside this new root. This will last for a long time.

Someone asked, is the aneurysm portion of the operation forever? Usually, they are forever. When you have a valve that looks like this, that's probably going to be almost forever, as well. This is really a major advance in valve surgery, especially for leaky valves.



Young Patients with BAV & Root Aneurysm



Dr. Joseph Bavaria: Now, bicuspid valves – what you saw before was a three-cusp valve.

This is a bicuspid valve. You can see we've already taken out the aneurysm on the left, and we have a bicuspid valve. In this kind of case, we can take that valve, put it back into this new aortic root, what's the new aneurysm repair and then repair the valve so that the coaptation zone – you can see that line right in the middle – is nice and what we call together. I'll show it here for everybody; we like to get what we call the position of prayer, a case where everything is perfectly stable and not have any holes in it, like you see there.



Surgical Outcomes for Valve-Sparing Root Repairs



Dr. Joseph Bavaria: Here's some of our personal data. This is our first 336 patients. We're probably close to 500 now.

As you can see, TAV is three-cuspid valves, and BAV is bicuspid valves. You can see that out to ten years, the results are really, really good for freedom from all-cause mortality.

You can see that number down at the bottom. It's only a 9 to 10% mortality rate at ten years, which is the normal for these patients. The average age of these patients is probably in their 50s. Then, freedom from reoperation is also very, very small. If you look at the line there where it says 10, it's 92 to 96. That means that there's only 4% or 5% reoperation rates, up to 10 years.



The bottom line is results are really, really good, and it doesn't seem to make much difference whether it's a TAV or BAV. As you can see, the lines are basically the same, so very, very good results with these cases with leaky aortic valves.

This is critical. When you have an aneurysm, this is a big deal because if you have an aneurysm, and your valve is pretty reasonable, you don't really want to throw that valve in the bucket. A lot of surgeons might do that, but we don't do that here. We're going to spare or repair your valve under those circumstances.

Adam Pick: Dr. Bavaria, we hear a lot about aortic valve replacement. Aortic valve repair, is that something that's done at all cardiac centers, specialized centers? Can you talk about the availability for a patient to actually have something like this even done?

Dr. Bavaria: Aortic valve repair is mostly in specialized centers at this point. Three-cusp aortic valve repair or three-cusp aortic valve sparing is a little bit more mature than bicuspid valve repair. Bicuspid valve repair is really only in a few centers at this point. It's getting better and better.

We have a 17-year experience with that. Our first one was done in November of 2004. We think this is part of the future, especially for leaky bicuspid and leaky tricuspid aortic valves.



Mitigating Operative Mortality



Dr. Jospeh Bavaria: This is research from Yale looking at whether a center that does a lot of cases does better.

What you can see here is that in the bottom part in the cases of a group that does 400 cases a year down at the bottom right-hand side, you can see that the mortality rate is very low for aortic surgery. You can see that if you go to a place that only does 25 where the green line is, then the mortality rate is a little bit higher. If a place does less than 25, I would tell you not to go to that, at least from the standpoint of this particular slide.



Image-Guided Planning for Bicuspid Valve Surgery



Dr. Joseph Bavaria: This is just to show you that we're doing some new research. This just from our engineering laboratories looking at bicuspid valves and how we're doing some next gen imagining and computing to try to figure out exactly how we're going to repair these valves before we even repair it.

We figure out on the benchtop before we even get into the operating room.



Minimally-Invasive Endovascular Aortic Replacement



Dr. Joseph Bavaria: This is a new first-in-human operation. Here's a picture of a dissection. I must say she was a Jehovah's witness so she wouldn't take blood. We couldn't do an open operation in her.

We basically did an aneurysm and an aortic dissection repair utilizing aortic stent grafts from basically the aortic valve, as you can see down there, all the way to the mid aorta. This actually was one of the first operations done utilizing this endovascular technology.



Lifelong Strategy for Aortic Aneurysm & Aortic Valve Disease



Dr. Joseph Bavaria: Now, lifelong strategy with aortic aneurysm and valve disease... My algorithm, or the way I approach it is:

First of all, repair whenever possible.

Number two, if you're less than 55 years old, repair, replace, maybe a ROSS procedure. If you're going to do that, large tissue valve ROSS procedure or mechanical valve.

If you're 55 to 70, we use surgical aortic valve with a tissue or a mechanical



valve with a root or ascending if necessary. This is guideline directed. The TAVR, people are asking a lot of things on the chat, TAVR, the average age for the low risk trials for TAVR is 72 to 74. Not many patients have been treated who are less than 65 with TAVR in the United States, at this point anyway.

Remember there's a high prevalence of bicuspid valve repair in patients under 70. TAVR is not quite as good in bicuspid cases as it is in tricuspid valve patients. Seventy to 80-year-olds, if their bicuspid is a low risk, we will do a straightforward aortic valve. If they're high risk, we will TAVR these patients.

If you're over 80, we'll try to TAVR you if we can.

Remember, screen all your relatives and be aggressive with aneurysms in young patients especially because the aortic part of the operation is forever.



Questions & Answers

Adam Pick: We've got 40 – actually, no, in total we've got 56 questions. I don't know that we're going to get to all of them but we're going to get right into rapid fire Q&A. This is coming from actually Michael Z. Dr. Bavaria, you might recognize the Z. He's one of your patients. He says, "Adam, is there any progress in the development of the use of TAVR procedure for patients with aortic regurgitation?"

Adam Pick: Thanks so much for the prepared remarks. We've got 40 – actually, no, in total we've got 56 questions. I don't know that we're going to get to all of them but we're going to try and just go into rapid fire Q&A. Michael asks, "Adam, is there any progress in the development of the use of TAVR procedure for patients with aortic regurgitation?"





Dr. Nimesh Desai: Yeah, so there is – we only do it in certain situations, although not in aneurysm patients because it doesn't fit very well in that situation, but there are some newer technologies coming out. None of them are commercially available in the US yet. Instead of the TAVR pushing on the calcium to stay in place, it actually grabs on to a leaflet to stay in place. I think there's stuff coming down the pipeline but there really isn't anything today that I would say is ready for primetime.



Adam Pick: Dr. Desai, you would say clinical trials are happening. Stay tuned. We need more data to figure out whether or not we've got a safe and effective device. Is that about right?

Dr. Nimesh Desai: That's exactly right. I think it's still pretty early phase in terms of getting commercially available here. I think we're years away from it.

Adam Pick: Great, and so Penn Medicine is participating in those clinical trials, correct?

Dr. Nimesh Desai: Yes, we're going to be in on everything that comes our way. We always have been.



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Adam Pick: Moving on to the topic of calcified heart valves from Donald. He asks, "Adam, my doctor indicated that my heart was not in the best shape because of calcium build up. Can you help me understand the progression of a calcified valve? Do most patients with calcified valves need heart surgery?"

Dr. Joseph Bavaria: Yeah, I'll answer that one. This is, first of all, the most common reason why valves need to be replaced is because of calcification of the valves. The calcification happens relatively slowly over a period of years. It's



not linear. In other words, the more calcified it gets, the faster it gets calcified. Eventually, a calcified valve will start to really lower the heart and the heart muscle is stressing. It's like a truck up a hill. That is when you end up needing – that's when you start getting symptoms and that's when you end up needing to have your valve replaced. One of the things that I think is interesting is that acquired valve disease, now three-cusp valve disease, actually happens faster than bicuspid aortic valve disease. That's new data from the last ten years. We didn't think that way beforehand. There's an interesting situation there. Acquired valve disease actually is more accelerated than congenital bicuspid aortic valve disease.

Adam Pick: When you say acquired aortic valve disease, is that just throughout your lifetime with your valves opening and closing versus being born with it?

Dr. Joseph Bavaria: Yeah, acquired disease means it's not congenital. You weren't born with it. About 3% to 4% of the entire population of the world will eventually have a calcified valve, just part of your genetics. This is a tricuspid valve. This is a normal valve. Bicuspid valve in general will almost always end up requiring a replacement before a normal lifespan of 85 to 90 years. That's a congenital issue.





Adam Pick: We're moving on to Ari. Ari asks, "Are there noninvasive techniques, like TAVR, to treat aortic aneurysms?"

Dr. Nimesh Desai: Yes, so we showed you that picture of the dissection TEVAR stent graft. The ascending aorta is a super hostile place for stent graft because it moves up and down and twists and grows bigger and smaller with every heartbeat. Although we do lots of stents to treat aneurysms in other parts of the aorta, this is still an area where things are pretty new. We've done probably about 25 or 30 of them, more than that, for very unusual scenarios that we've run into over the years. Let's say that's 30 out of how many ascending aortas have we done over that timeframe, maybe 3,000. It's a very small proportion of them.



Adam Pick: Do you think the prevalence of that procedure will increase over time or it's still we don't know?

Dr. Bavaria: I think it'll increase over time, but it's not quite ready for primetime, especially in the ascending aorta. I think in ten years, we'll have more – it'll be better, but we're working on it pretty aggressively but we're not quite there yet.





Adam Pick: Moving on to echocardiograms, which are often very confusing for patients. Here's a question from Lou. He says, "What echocardiography parameters do Dr. Bavaria and Dr. Desai feel are the most significant when monitoring a BAV?"

Dr. Nimesh Desai: Right, so we're looking at the degree of stenosis or narrowing and we're looking at how much leakage there is and we're looking at how big the aorta is. Those are the three things. The third one, CAT scan is probably just as important, but the other two you can only derive from echo. Of those, the valve leakage there is different ways to quantify them. That's a little bit more complicated, but for the stenosis side, which is the majority of patients, we're usually looking at something called a valve area, the mean gradient, and the what we call peak velocity. The one that's the most correlated with developing symptoms is the peak velocity. That's how fast the blood goes through the aortic valve. Imagine it's like putting your thumb on a hose, that if you make the hole smaller, the water pours out faster. It's the same thing with the aortic valve. When the hole gets smaller, the blood comes out in a faster and faster rate. When that number hits four meters per second, that's when you know you have a severe stenosis.





Adam Pick: Let's move on to aneurysm devices. We talked about this a little earlier. Jerry asks, "Adam, we hear a lot about the different heart valves out there, but what about aneurysm devices? How are those devices changing?"

Dr. Joseph Bavaria: That's a good question. They're not really changing that much. The grafts that we use to – it's like pipe fitting 101. We basically take the aorta out, the pipe out, and then we put a new pipe in. The new pipe is made out of a woven material graft. These are very tightly woven grafts. It's a textile. The closest I could tell you, it's a little bit like a sail on a sailboat which doesn't let any air through, but it can move around. It can take the curves. These grafts have been approved over time. The don't bleed as much as they used to. In fact, they don't bleed at all now. It lasts a long time. In fact, it lasts forever. They're very good, but they're what I would call iterative changes in the graft. They're getting better but it's not a giant leap. The giant leap is what we just talked about five minutes ago, which is endo grafting of the aorta in the ascending aorta. As Dr. Desai says, the ascending is a particularly hostile area, but we're working on it.





Adam Pick: Moving on to Nick, some procedure we haven't talked about yet today which is the Ozaki procedure. He asks, "What should I know about the Ozaki procedure for aortic valve disease? Is it used for both adults and children?"



Dr. Joseph Bavaria: Yeah, first of all, the Ozaki procedure, sometimes with the Ozaki procedure, you need to go back to history. The Ozaki procedure was invented for places that don't have enough capital or whatever to actually do open heart – open, I mean, valve surgery, places like the lower income countries of the world because you're using your own pericardium so it's basically a free valve. Now, Dr. Ozaki himself has a pretty good result but we still haven't really had excellent or robust verification of those results. One of the things that – so I actually don't do the Ozaki procedure because I'm not really quite sure that it's the right thing to do. Remember, you're using your own pericardium and – I don't know. The valve companies spent billions of dollars figuring out pericardial valves, so I'm not quite in the Ozaki camp at this point, but I'm not going to say that it's not a decent procedure, but that's just my personal opinion. I don't know what Nimesh would say.

Dr. Nimesh Desai: Yeah, and I would agree. I think it's a very niche procedure. I think in countries that can't afford prosthetics, it's a good procedure. In certain situations with infection apparently, it's a good procedure. If you have a very small root, it can be a nice procedure as well. I think there are a lot of questions about long-term durability with it.





Adam Pick: Great, well, we have time for one more question. I think we can end this on the idea of risk because that's something that patients often have is what is my risk going into heart surgery. Shirley asks, "What is the risk of an aortic valve and aneurysm surgery for an 83-year-old patient?"

Dr. Joseph Bavaria: So this is the risk of both an aortic valve and an aneurysm. For the 83-year-old patient, the risk is not zero. That's for sure. In places like our place where we do a ton of these things, the risk is probably not that great from the actual surgery itself from a standpoint of death. There might be a certain issue. If your lungs are bad, you could die from a pulmonary issue later on, but if you're in robust health, your risk of death from the operation is probably pretty low, like 2%, 3% or so. The biggest risk at 83 years old, there would be a slight risk of stroke. I think that in our practice anyway, we still aren't really thinking about not doing cases at 85 or 86. In my personal practice, open aneurysm surgery, valve surgery, exactly like this question, my oldest patient is 88.



Adam Pick: Unfortunately, we are running out of time, but please don't exit the webinar just yet. I want to extend a tremendous thank you to Dr. Bavaria, Dr. Desai, the Penn Medicine team for supporting us and getting us all together to talk about the advances in aortic valve and aneurysm surgery. Dr. Desai, Dr. Bavaria, thank you so much.

Dr. Bavaria: Thank you.

Dr. Desai: Thank you.

Adam Pick: To all the people on the call today, I want to thank you for taking the time, getting educated, learning about aortic valves and aneurysms so you feel educated and empowered. With that said, we're going to wrap up the webinar. If you could, please complete the survey that is coming up on your screen right now. Thanks so much!



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.

- <u>Adam's Free Patient eBooks</u> Download 10+ free eBooks about heart valve disease and treatment options.
- <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.
- <u>Adam's Heart Valve Blog</u> Get the latest medical news and patient updates from our award-winning blog.
- <u>Educational Videos</u> Watch over 150 educational videos filmed by the Heart-ValveSurgery.com film crew about heart valve surgery.

