

ADVANCES IN HEART VALVE REOPERATIONS



Featured Speakers



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Joy Marks

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[Please note: A complimentary video playback of this eBook is now available on YouTube at this link.](#)

Introduction



Advances in Heart Valve Reoperations




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Joy Marks
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Adam Pick
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Adam Pick: Hi, everybody. My name is Adam Pick. I'd like to welcome you to the webinar titled, "Advances in Heart Valve Reoperations." If I have yet to meet you, I'm the patient who started HeartValveSurgery.com over 15 years ago. The mission of our website is simple. We want to educate and empower patients like you. This webinar, which has had registrations from over 730 people around the world, was designed to support our mission.

- Introductions
- Heart Valve Overview & Treatment Options
- Reoperation Techniques
- Valve-in-Valve: No More Surgery?
- Patient Spotlight: Joy Marks
- Webinar Survey

Throughout the webinar, you're going to be in what's called "listen-only" mode, but I encourage you to submit your questions in the control panel that's on your screen. I'll explain why as we look at the agenda. We're going to introduce the featured speakers. We're going to talk about heart valve disease and treatment options. We're going to look at some of the latest and greatest re-operative techniques, including whether-or-not Valve-in-Valve is the end of surgery. We're going to have a wonderful patient spotlight. Then, I'm going to ask you to complete a very quick five-question survey at the end of the webinar.




- 80 Years Young from Chicago, IL
- Teacher for 30 years
- Enjoys dancing, yoga and walking
- 2014: Mitral Valve Replacement
- 2022: Mitral Valve-in-Valve Procedure


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Adam Pick: Now, for the featured speakers, it is a gift that we're going to be talking to Joy Marks who is 80 years young from Chicago, Illinois. She's been a teacher for over 30 years. She enjoys dancing, yoga, and walking. In 2014, Joy had a surgical mitral valve replacement. Recently, a few months ago, she had a mitral Valve-in-Valve reoperation using transcatheter techniques. We're going to talk to her all about her experiences. Joy, thanks for being on the line with us today.

Joy Marks: You're welcome.

 HeartValveSurgery.com


Dr. Charles Davidson



- Professor of Medicine
Clinical Chief, Division of Cardiology
Northwestern University Feinberg
School of Medicine
- Medical Director, Bluhm
Cardiovascular Institute,
Northwestern Memorial Hospital
- Clinical trial specialist for PARTNER,
EVOQUE, EARLY TAVR, PASCAL, REPAIR MR
and more.
- Consultant to and receives grant support
from Edwards Lifesciences


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Adam Pick: Now let's introduce the physicians. I am honored that they're taking time away from their very busy practice at Northwestern Medicine. We are thrilled to have [Dr. Charles Davidson](#) with us today. He's the professor of medicine clinical chief division of cardiology at Northwestern University Feinberg School of Medicine at Northwestern Memorial Hospital. He is a clinical trial specialist having worked on some of the largest, most transformative valve clinical trials including the PARTNER trial, EVOQUE, Early TAVR, PASCAL, and Repair MR and many more. He's a consultant to and receives grant support from Edwards Lifesciences.

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Dr. Christopher Mehta

- Attending cardiac surgeon at Bluhm Cardiovascular Institute at Northwestern Memorial Hospital
- Assistant professor of surgery (cardiac surgery) at Northwestern University Feinberg School of Medicine.
- Specializes in minimally invasive, complex valve surgery including TAVR, valve-in-valve procedures
- Focus on aortopathy including root repair and replacement.
- Consultant to W.L. Gore & Associates



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Adam Pick: We are also happy to welcome [Dr. Christopher Mehta](#) who's an attending cardiac surgeon at Bluhm Cardiovascular Institute at Northwestern Memorial Hospital. He's the assistant professor of cardiac surgery at Northwestern University Feinberg School of Medicine. He specializes in minimally invasive complex surgery including TAVR, transcatheter aortic valve replacement, and Valve-in-Valve procedures. He has a focus on aortopathy, including root repair and replacement of aortic aneurysms. He's a consultant to W. L. Gore & Associates. Dr. Davidson and Dr. Mehta, thanks so much for being with us today.

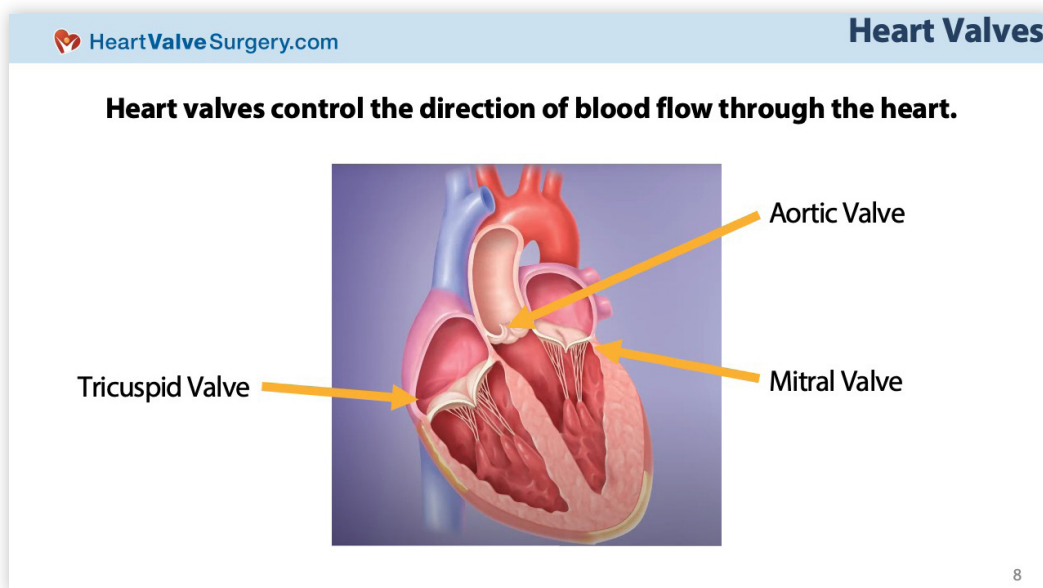
Dr. Christopher Mehta: A pleasure to be here. Thanks, Adam.

Dr. Charles Davidson: Thank you, Adam. I appreciate that.



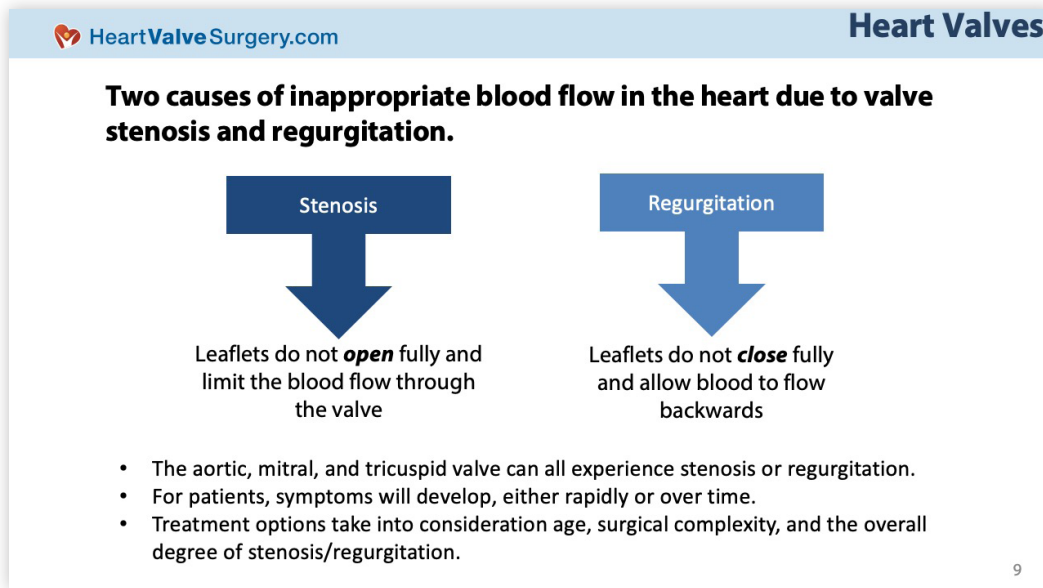
Adam Pick: I could go on-and-on about the achievements of Dr. Davidson, Dr. Mehta, and the entire team at Northwestern Medicine. What I'd like to do, though, is show you this. You can see all these smiling faces on the screen in front of you. These are patients in the HeartValveSurgery.com community who have gone to [Northwestern Medicine](#) and had care, wonderful care, excellent surgical outcomes, excellent interventional outcomes from doctors including Dr. Davidson, Dr. Mehta, and the entire Northwestern team. It's great to be and know these people and see how they're smiling in these photos. With that said, I'd like to welcome this wonderful group of people, Joy, Dr. Davidson, and Dr. Mehta.

Heart Valve Anatomy




Dr. Christopher Mehta: Let me just start with an overview of anatomy and what we're talking about here. At a real basic level, heart valves control the direction of blood flow through the heart. There are four valves. We're going to focus on these three because these are the ones that we most commonly see disease in. On the right side of the heart is the tricuspid valve, which is between the right atrium and the right ventricle. Then blood goes from the right ventricle to the lungs and comes back on the left side of the heart and the left atrium. Then, the mitral valve sits between left atrium and left ventricle. The left ventricle then ejects blood through the aortic valve into the aorta where we get blood to our brain, our organs and the rest of our body.

Heart Valve Problems



Dr. Christopher Mehta: You could have two major issues with heart valves, one being a narrowing of the valve, also known as stenosis, where the leaflets do not open fully and it limits blood going through that valve. The other issue is regurgitation, which is also known as a leaking valve. That's where the leaflets may not necessarily close onto themselves together and so blood can flow backwards. The aortic, mitral, and tricuspid valve can all experience one of these two problems. When we're thinking about treatment options, there's a lot to consider: age, the complexity of what's going on, and the overall degrees of these two issues.

Aortic Valve Disease: Indications & Treatments

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Aortic Disease: Indications & Treatments

Aortic Stenosis (AS)

- Higher pressures in the left ventricle
- Thickening of the left ventricular
- Weakening of the left ventricular muscle (heart failure)
- Symptoms of shortness of breath, chest pressure and/or lightheadedness

Age	Treatment Options
>70	TAVR
60-70	TAVR vs. Mini-thoracotomy AVR
<60	Mini-thoracotomy AVR
< 50	Mini-thoracotomy AVR with mechanical valve vs. Ross procedure

Aortic Regurgitation (AR)

- Can develop suddenly or over decades; once severe, surgical treatment is often required
- Aortic valve does not close tightly
- Blood pumped out of left ventricle leaks back into it
- Symptoms of shortness of breath, chest pressure and/or lightheadedness

Treatment Options
Surgical valve repair/mini-thoracotomy AVR
TAVR devices in trials

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Dr. Christopher Mehta: When we look at aortic disease in particular, aortic stenosis is that narrowing of the aortic valve. What can happen is it can cause the left ventricle to be working really hard to pump blood across a narrowed valve. Then, there's a higher pressure in that left ventricle and it compensates by actually thickening. The heart is a muscle so it will get thicker and stronger, but eventually, it can only do so much. That leads to a weakening of the muscle which can develop into heart failure. Common symptoms are shortness of breath, chest pressure, lightheadedness, sometimes even fainting. We're going to talk about this a little bit more treatment options here but it basically falls into the realms of either surgery or a transcatheter aortic valve replacement. A lot of this does depend on age, so younger folks tend to get surgical option, and then as we get older, especially older than 70, we tend to prefer a transcatheter aortic valve option for those patients.

The other issue is regurgitation, that is leakiness through the valve. This can happen acutely, meaning all of a sudden, or it can be chronic, meaning it happens over a long time. Once it's severe, you typically need some form of intervention. Again, symptoms include shortness of breath, chest pressure, and you could have lightheadedness. Treatment options are more in the realm of surgery. Sometimes we can repair the valve surgically. Sometimes we replace it. There are some transcatheter options currently in trial but again, the mainstay for now is surgery.

Adam Pick: Dr. Mehta, for some of the patients out there who might be newly diagnosed, they're seeing this term "mini-thoracotomy". Can you explain to the patients what that might be compared to a traditional sternotomy?

Dr. Christopher Mehta: Sure, so traditionally, this was done with a full breastbone incision that would go through the full breastbone. We've had advances in techniques in surgery the same way we've had advances in transcatheter. Now, we have more minimally invasive options for replacing the aortic valve. I'd say, at least at Northwestern, we tend to do more of the minimally invasive options, such as mini thoracotomy, for example, where we actually just go between the ribs so we don't even need to go through the breastbone. Another option is a partial or a mini sternotomy where it's a partial breastbone instead of the full breastbone.

Mitral Valve Disease: Indications & Treatments

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 Mitral Valve

Mitral Valve Disease is the most common form of heart valve disease in the United States accounting for more than 500,000 hospital admissions per year.

Mitral Regurgitation (MR) <ul style="list-style-type: none"> • Higher pressure in left atrium and pulmonary veins • Left atrium enlarges to accommodate increased volume • Symptoms include shortness of breath, fatigue and exercise intolerance, rapid, fluttering heartbeat, and chest pain 	Mitral Stenosis (MS) <ul style="list-style-type: none"> • Decreased blood flow to left ventricle/body • Fluid builds up in lungs due to inability of atrium to decompress • Symptoms include shortness of breath, swollen legs 	Mitral Valve Prolapse (MVP) <ul style="list-style-type: none"> • Blood flows back into the left atrium due to a misalignment of the leaflets • Can progress to severe MR • This is the most common heart valve condition in the United States. • Symptoms include rapid, fluttering heartbeat, dizziness or lightheadedness, shortness of breath, fatigue and chest pain
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Based on symptom severity, surgery or transcatheter intervention is often recommended after medical management has been exhausted

Unless progression to severe MR or symptoms, majority of patients are medically managed.

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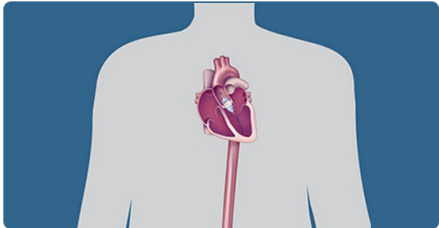
Dr. Christopher Mehta: Now, let's talk about the mitral valve. Mitral valve disease is the most common form of heart valve disease in the US. Again, we're talking about mitral regurgitation, leakiness, where blood backs up into that left atrium. Again, the left atrium accommodates the increased blood volume to some degree, but eventually, you can develop symptoms. Stenosis is that opposite problem where it's a narrowing of the valve where you get decreased blood flow to the left ventricle. Then fluid could build up in the lungs. It can lead to a backup, if you will, of blood leading to symptoms. Now, for these we have surgery and transcatheter interventions as well. These typically come after we've exhausted medical management and once those diseases get in their more severe form. Mitral valve prolapse now falls in the realm of the mitral regurgitation. This is a misalignment of the leaflets.

Treatment Options

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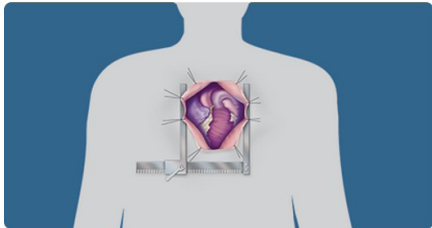
Treatment Options

Transcatheter Valve Replacement (Aortic, Mitral, and Tricuspid) and Repair (Aortic).



The transcatheter procedure allows a new valve to be **inserted within** the native, diseased valve.

Surgical Valve Replacement or Repair for Aortic, Mitral, and Tricuspid.




During open heart surgery, the surgeon **removes** the diseased valve and replaces it with either a mechanical or biological valve (made from animal or human tissue).

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Dr. Christopher Mehta: In terms of treatment options, very broadly speaking, we have two types for all those valves. One is transcatheter valve replacement. This is where we're able to insert a wire into an artery or a vein, a blood vessel, and then under live x-ray, we can put that wire across the valve and then we can insert a new valve within the native diseased valve. This is more minimally invasive. The surgical valve replacement is open heart surgery. It requires cardiopulmonary bypass, the heart lung machine. This is where a surgeon can physically remove the diseased valve and replace it with either a mechanical or a biological valve.

Surgical Valve Replacement

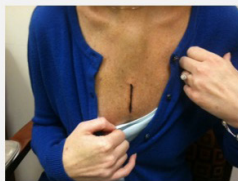
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Surgical Valve Replacement

Standard surgical valve replacement (open heart procedure) is the most common treatment for stenosis/regurgitation and has been performed for many years.

Open Heart Surgery - Sternotomy

During open heart surgery, the surgeon will make an incision in the middle of your chest. The surgeon will open and expose the poorly working valve. The new valve will be stitched into place.



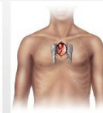


Minimally Invasive Alternatives

Minimally invasive incisions have been shown to be equally safe and even superior to conventional sternotomy. These approaches result in less bleeding, lower rates of atrial fibrillation and pneumonia, and quicker post-operative recovery.

Conventional

Minimal Incision






Open-chest or Sternotomy
Right Anterior Thoracotomy
Mini-sternotomy

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Dr. Christopher Mehta: These are the options for surgical valve replacement. Sternotomy means a full breastbone incision. Again, we're doing a lot of more minimally invasive options at Northwestern Medicine. That picture you see on the right, that's what would be called a partial sternotomy or a mini sternotomy where we just have to go through part of the breastbone, not the whole thing. Down in the bottom right, we have a right interior thoracotomy, that's also known as that mini thoracotomy approach, or we can go between the ribs. These incisions are about four or five centimeters. They're not as large as the conventional traditional sternotomy.

Why Do Replaced Heart Valves Fail?

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Why Do Replaced Valves Fail?

Depending on the type of valve selected, there is a longevity associated with it.

Valve Type	Description	Expected Longevity	Anticoagulation Need
Mechanical	Made of special carbon compounds and titanium	Often lasts the patient's lifetime	Yes - indefinitely
Bioprosthetic (Tissue)	Made from animal (bovine/cow) or human tissue	Upwards of 15 years from surgery	No

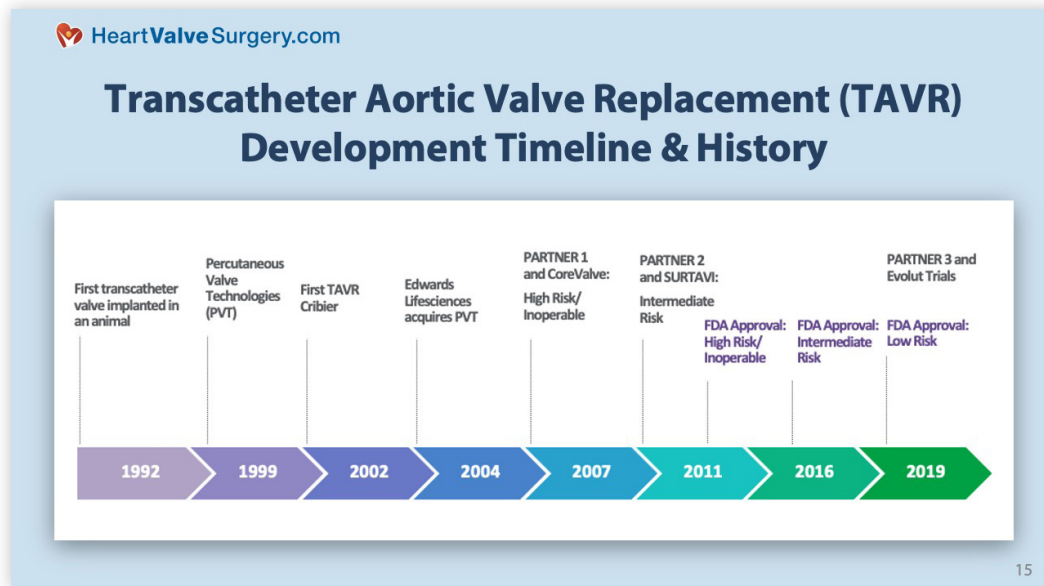
- Much like the causes of initial failure, both mechanical and bioprosthetic valves are at risk of developing stenosis and/or regurgitation from the following complications:
 - Leaflet degeneration
 - Endocarditis leading to leaflet destruction
 - Clot or pannus formation on leaflets
- For patients, who were once deemed appropriate surgical candidates, facing a second re-operation comes with unique challenges and risks, some of which prohibitive.

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Dr. Christopher Mehta: Why do replaced valves fail? This is a question very important to this particular webinar. When I counsel patients on surgical valves and the type of valve to choose, there are pros and cons to both. Let's start with the mechanical valve. Mechanical valves are made of certain carbon compounds and titanium. The benefit of the mechanical valve is that it often will last the rest of the patient's life, meaning once you place it in, in theory, you should not need surgery ever again. The downside is that you need blood thinners in order to get a mechanical valve, because if you don't have blood thinners, the valve can form clots on it and it can make it not work. Now, I say in theory the patient may not need surgery in the future because from time to time, very rarely, we do sometimes see patients who need a replacement of a mechanical valve. That tends to be more for issues like infection and less because the valve itself is failing.

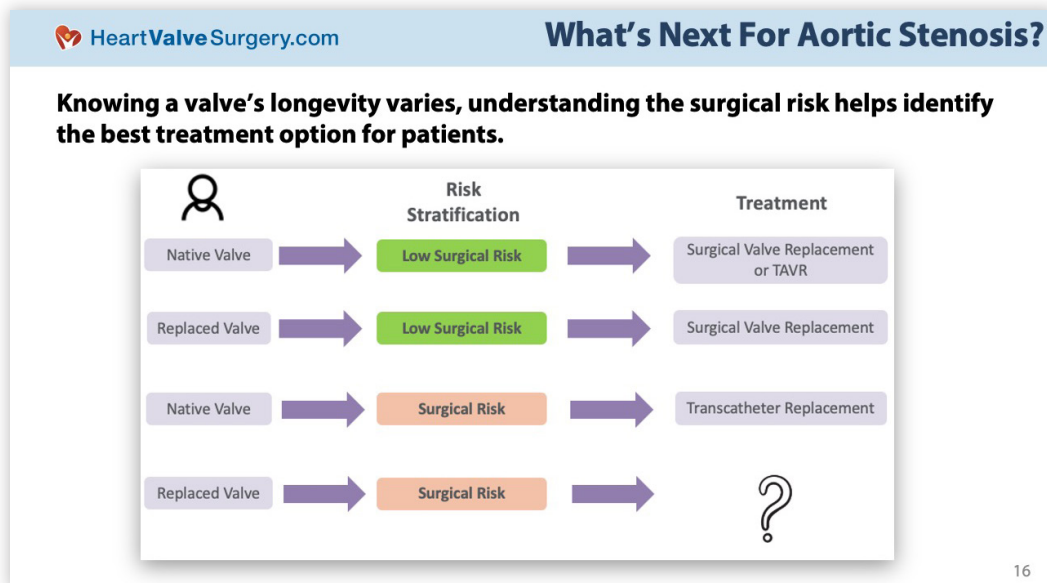
The other option is a bioprosthetic valve. These valves are typically made from animal tissue, cow or pig, sometimes human tissue. Compared to mechanical valves, you don't need long-term blood thinner, anticoagulation. That's good. The downside is they have a certain durability longevity to them. It depends if it's aortic versus mitral versus tricuspid, but typically, we're speaking about 15 years or so from surgery. Then you need to think lifelong what's going to be the next option, for example. Much like stenosis or regurgitation of those valves, the tissue valves can also eventually degenerate as well. Again, you need to plan in the future what's going to be the next step after we've replaced a tissue valve.

Transcatheter Heart Valve Replacement History



Dr. Christopher Mehta: Let's talk about transcatheter aortic valve replacement, also known as TAVR, because over the course of the last two decades we've really made tremendous strides in this minimally invasive technology. The first in-human TAVR was performed in 2002. Both balloon expandable valves and self-expanding valves underwent clinical trial, first in patients who were high risk and inoperable followed by intermediate risk followed by low risk. Now, we have FDA approval actually for all ranges, that is patients who are low risk to patients who are even high risk and inoperable, for both of the commercially available valves.

What's Next for Aortic Stenosis Therapy?



Dr. Christopher Mehta: We need to know the longevity of the valve with respect to the patient's age and comorbidities because any time we're implanting a valve, we need to think about what may be the next step in the future, right? If a patient is a low surgical risk, and especially if they're on the younger side, we tend to favor surgical valve replacement in those patients with an understanding that they may, in the future, if they need it, can get a Valve-in-Valve procedure, which we'll talk about. Older patients, maybe patients at higher surgical risk who may struggle with surgery. So, transcatheter may be a better option there.

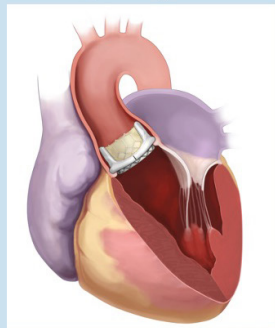
Valve-in-Valve: History In The Making

Valve-In-Valve (ViV): History In The Making

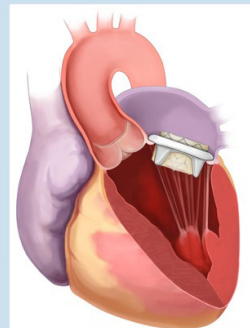
For patients with failing surgically replaced valves, non-surgical options were limited until the transcatheter valve replacement emerged

- **Therapy:** transcatheter valve-in-valve

A new transcatheter valve is tightly placed into the orifice of the failed surgical valve, pushing the old valve leaflets aside



Aortic Valve-in-Valve




Mitral Valve-in-Valve


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Dr. Christopher Mehta: This is where Valve-in-Valve comes in. Now, Valve-in-Valve, that term, implies that there is a previously implanted valve and we're placing a new valve within the failing previously placed valve. What you see here on the left is an aortic valve prosthesis, a patient who's gotten a surgical aortic valve, and then on the right, a patient who's had a previous surgically placed mitral valve. With Valve-in-Valve, transcatheter, meaning a wire across that valve, we can place a new valve within the old valve once it has failed.

Who Is A Candidate for Valve-in-Valve?



Valve-In-Valve: Who Is A Candidate?

Symptoms	Treatment Recommendations
Intractable Hemolysis or Heart Failure attributable to prosthetic transvalvular or paravalvular leak	Surgery, unless risk is high or prohibitive
Asymptomatic patients with severe prosthetic regurgitation and low operative risk	Surgery
Prosthetic paravalvular regurgitation with the following	Percutaneous Repair of Paravalvular leak
(1) Intractable hemolysis or NYHA Class III or IV symptoms	
(2) High or Prohibitive Surgical Risk	
(3) Anatomic features suitable for catheter-based therapy	
Severe Heart Failure Symptoms caused by bioprosthetic valve regurgitation who are high to prohibitive surgical risk	Transcatheter ViV procedure 

Otto et al. (2020, December 17). ACC/AHA Guidelines for the Management of Patients with Valvular Heart Disease: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines.

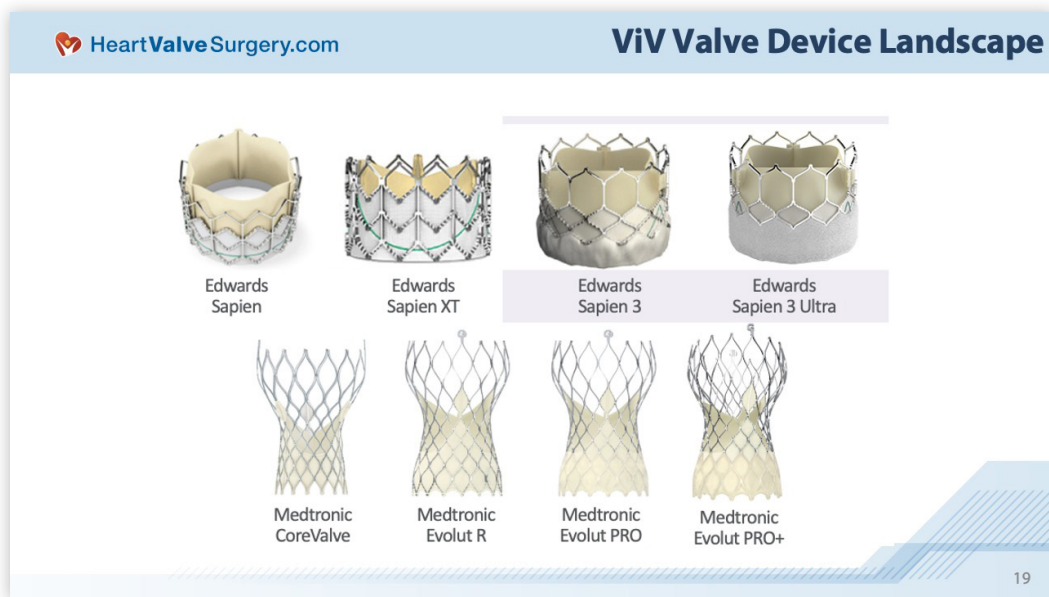
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Otto et. al. (2020, December 17). ACC/AHA Guidelines for the Management of Patients with Valvular Heart Disease: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines.

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Dr. Christopher Mehta: The question becomes, well, who's a candidate for Valve-in-Valve? There's no straightforward answer here. It's a nuanced thing, which is why Dr. Davidson and I and our interventional cardiology and surgery colleagues meet in a heart valve team multidisciplinary meeting to review everybody's cases and see who would be a candidate for Valve-in-Valve versus who we think may be better served with a reoperation surgery. There are a few things to take into consideration here: age, surgical risk, the symptoms a patient is having, and perhaps more importantly, the anatomical findings that we're seeing on echocardiogram and on CT scan, because a lot of that tells us whether a patient may be better served with Valve-in-Valve versus a patient who may just need a second reoperation now with an anticipation of Valve-in-Valve in the future.

Valve-In-Valve Landscape



This is the Valve-in-Valve device landscape currently and in particular for the aortic valve. We have the Edwards balloon expandable valves and the Medtronic self-expanding valves. They have gone through different generations and the valve technology keeps improving and so we're seeing better and better results with Valve-in-Valve.

Criteria for Selecting Valve-in-Valve Devices


Adam Pick: Dr. Davidson, for patients, and I'm actually curious to know about this, when you talk about the Edwards valve versus the Medtronic valve one, expanding one, I think you said self-expanding, what does that mean?

Dr. Charles Davidson: That's a good question. The balloon expandable, or those four across the top, basically is made of a metal that needs to be expanded with a balloon. It used to be stainless steel. Now they're cobalt chromium frames. As you can see, it's a slightly smaller footprint, if you will, in the valve. Material, which is bovine pericardium, is mounted inside of that so it becomes an annular type of valve. The self-expanding means that, once you release the valve that's made of metal, it expands on its own and its dimensions are calculated for both of these valves based on CAT scans that we've obtained with the patients ahead of time. The Medtronic valve is made of porcine or pig pericardium. It's a supra-annular valve, so not at the annular level, but you can see that it's a little bit larger footprint. It's just a matter of what type of metals that are used and then how they anchor to the native valve, or in the Medtronic situation, also to the aorta.

Adam Pick: Is it dependent upon, I'm guessing, I don't know, the patient's anatomy that you might prefer to use one valve over the other or is there some other criteria that you use to help you figure out which valve to use?

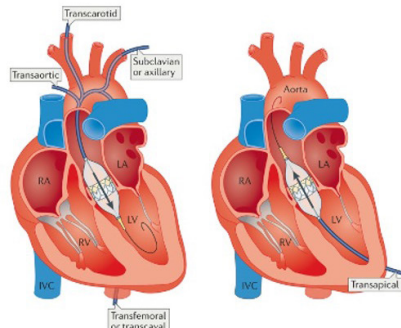
Dr. Charles Davidson: This is probably the subject of an entirely full hour, but there are reasons to pick one over another. Some are local choices where certain centers prefer one over another. There are data that suggest that maybe one is preferable in certain circumstances than another. I guess I would encourage people to have this discussion with their cardiologist and cardiac surgeon to understand what might be the best valve choice for them. Just like anything that's not one size fits all, not one product suits all. Anatomy is certainly a key factor in valve selection.

Access Points for Valve-In-Valve

 HeartValveSurgery.com
 ViV/TAVR Access

The ViV/TAVR procedure uses a catheter to insert the new valve within your replaced valve. The frame will use the leaflets of the previous valve to secure it in place.

The procedure can be performed through multiple approaches:



Transfemoral (preferred)
Through an incision in the leg vein or artery

Transcatheter
Through an incision in the left carotid artery

Transcatheter
Through an incision in the chest between the ribs

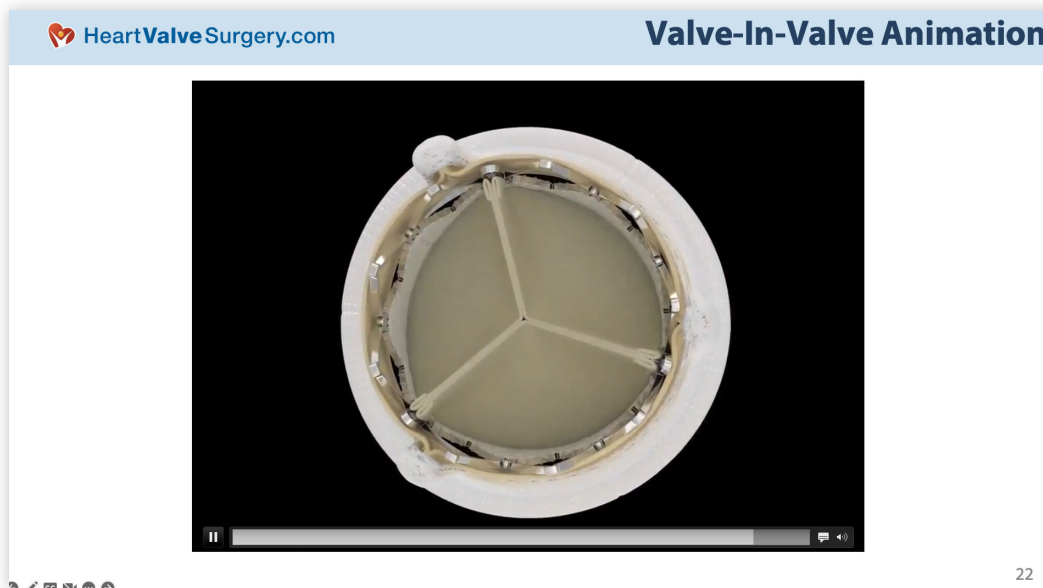
Transcatheter
Through an incision in the upper chest

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Dr. Christopher Mehta: As far as access for doing the transcatheter procedure, we typically prefer to go through the artery in the groin, which is the femoral artery. So most of the time, that's the approach we'll take to get a wire around to the heart. Sometimes, we can't do that due to anatomical reasons, and so we have another – a number of other options we can use as well. For example, sometimes we go to the carotid artery in the neck. Sometimes, we make a small incision in the chest between the ribs and then sometimes we can actually go through the upper portion of the aorta itself. We have a number of different options in case we can't go through the femoral artery.

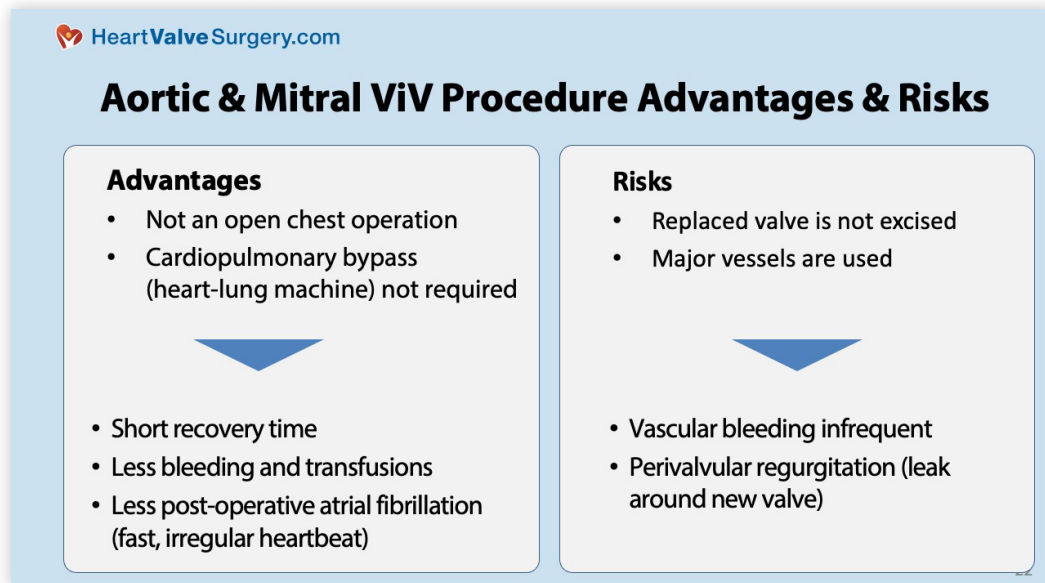
Video: Valve-in-Valve Procedure



Dr. Christopher Mehta: Then this is [an animation that's going to show you how we perform a Valve-in-Valve procedure through a femoral artery approach](#), the artery in the groin. The first thing is we place a wire from the femoral artery around – through the previously placed aortic valve that you can see on the screen into the left side of the heart. Then, we bring a valve that's mounted onto a balloon around into place basically where the previous valve was. We have a temporary pacemaker in the heart with which we could use to pace the heart and that allows us to deploy the balloon and put the new valve within a valve, so it's sort of like a stent. Then we take everything out.

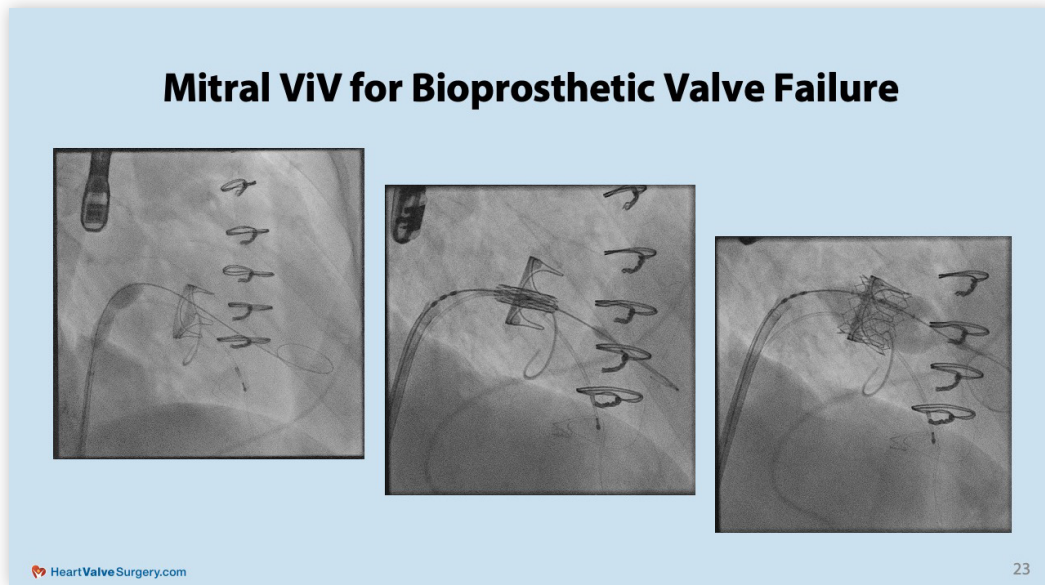
You can see in this image the new valve has actually pushed the old valve leaflets out of the way, and now it's working as the new valve. This is called Valve-in-Valve.

Advantages & Risks for Valve-in-Valve Procedure



Dr. Christopher Mehta: When talking about Valve-in-Valve transcatheter procedures for aortic and mitral valves, the benefits here are that you don't have to go back in the chest. It's not an open chest operation. It doesn't require the heart-lung machine, cardiopulmonary bypass. It tends to lead to shorter recovery times, less blood transfusions, less incidents of post-operative irregular heartbeats including atrial fibrillation. There are still risks, of course, and this is not for everybody. We always review in a multidisciplinary fashion whether a patient would be a candidate for this kind of procedure. For one, the previously placed valve is not removed. We're pushing the leaflets out of the way. We are using major blood vessels, including the femoral artery and we're putting wires in the aorta. So, we do have to be cognizant about bleeding complications that can occur, although they are not frequent. Then any time we're looking at previously placed valves, we worry about a leak around the new valve, called a perivalvular leak. These are just some of the considerations we have when assessing somebody for a Valve-in-Valve procedure.

Mitral Valve-in-Value for Bioprosthetic Valve Failure



Dr. Christopher Mehta: These three frames demonstrate a mitral Valve-in-Value for a patient who's previously had a surgically placed valve. We're placing a wire through a blood vessel and across the previously placed valve. Next, we bring in the new valve in the second frame over a balloon. Then when everything looks good, we inflate the balloon, which then leaves the new valve within the old valve and functions as a new working valve.

Mitral Valve-in-Valve Pressure Gradient

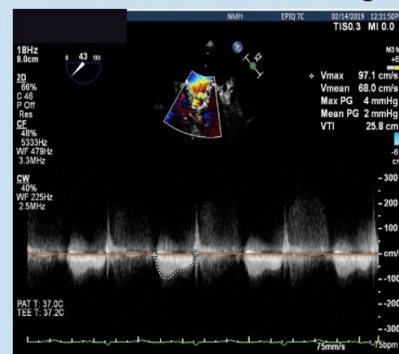
Mitral Valve-In-Valve

A successful ViV will demonstrate a reduction in the pressure gradient across your valve and symptom improvement.

Pre-Intervention = 15 mmHg



Post-Intervention = 4 mmHg



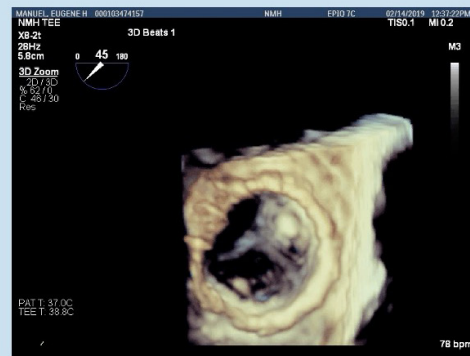
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Dr. Christopher Mehta: These are images from an echocardiogram looking at how well the valve is functioning. Before the intervention, the gradient, the pressure gradient across the valve is high. That number, 15, is high. You can see after the intervention, it comes down to a more normal, appropriate number, meaning that the valve is working better.

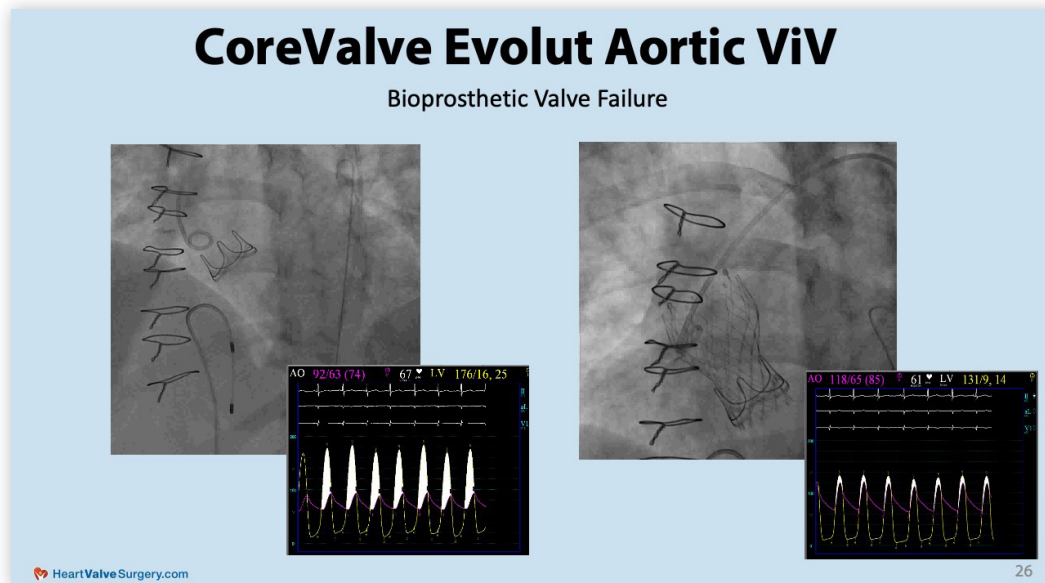
Mitral Valve-In-Valve

A successful ViV will demonstrate a reduction in the pressure gradient across your valve and symptom improvement.



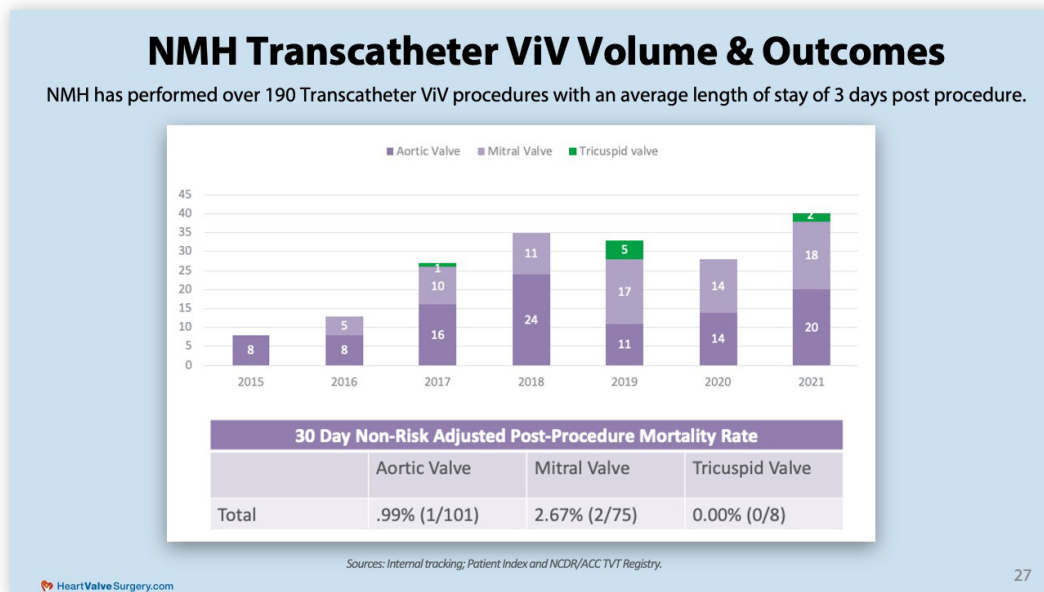
This is three-dimensional echocardiogram, which is just showing how the leaflets of the new valve open. So, you get a good sense that it's working well here.

CoreValve Evolut Aortic Valve-in-Valve



Dr. Christopher Mehta: Then this is an aortic Valve-in-Valve procedure. If you look at the frame on the left, that crown-shaped thing is the previously surgically placed aortic valve. Then on the right, we've placed a new valve within that valve. Then the hemodynamic tracings that you see at the bottom just demonstrate that there was an improvement in that gradient again, and the valve is working much better than the old, previously placed valve.

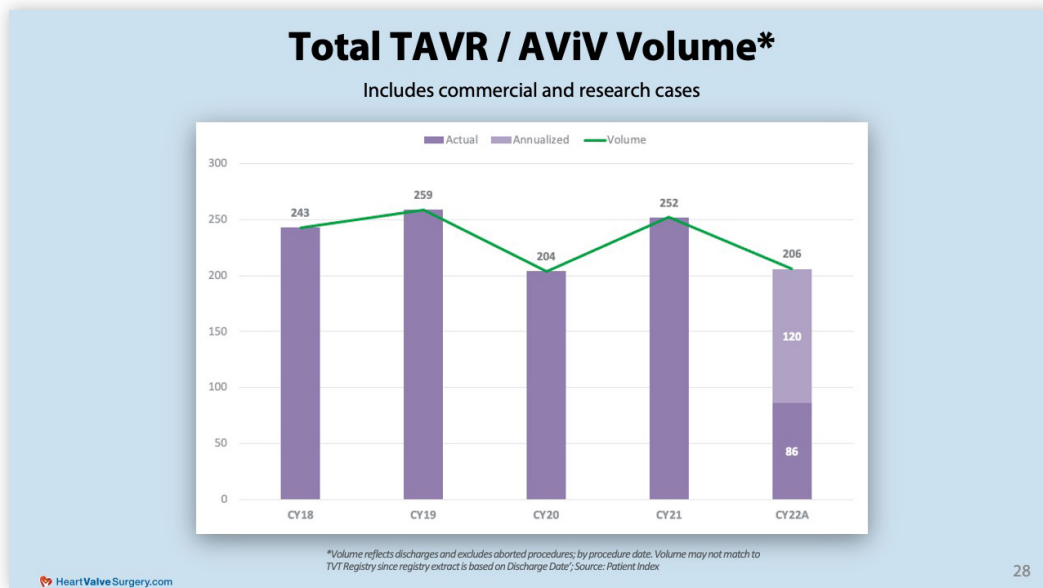
TAVR/Aortic Valve-in-Valve versus Surgical Volume



Dr. Charles Davidson: I want to give you some flavor of what we've been doing at Northwestern Medicine. We've been doing these procedures for a number of years. You can see we started back in 2015 with just a handful of these. We've done over 190 thus far, probably over 200 now into this year. This only goes through 2021.

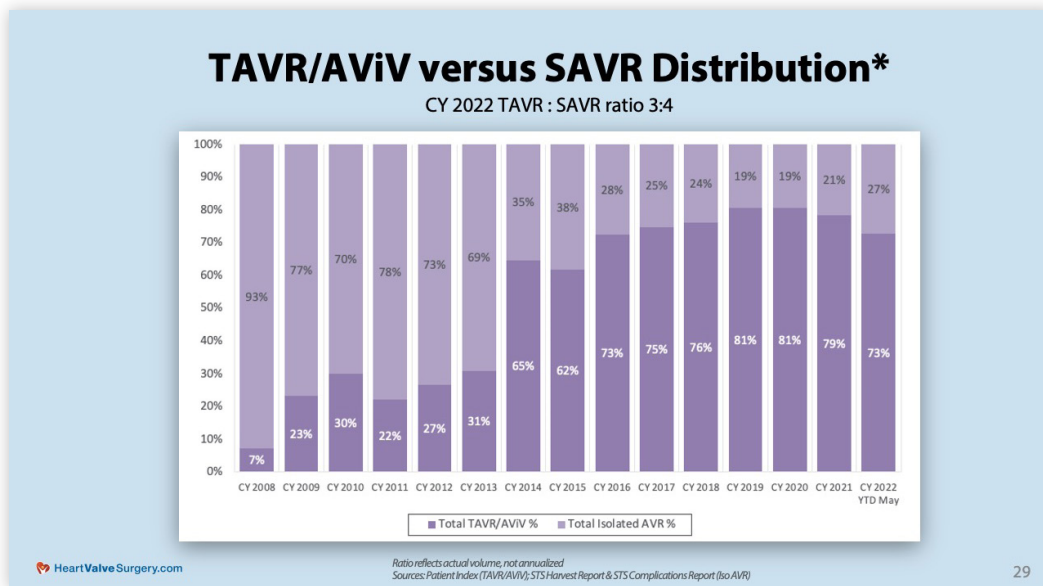
Average length of stay is three days. I think what we're most proud of this is not just the growth but the very low mortality rate. Only one out of the first one hundred that were done here, two mitrals and zero on the tricuspid side. It speaks to the safety of the procedure. This is not a procedure for everybody, and it does require a multidisciplinary approach to understand whether you're the best candidate for it or not.

Aortic Valve-in-Valve Volume



Dr. Charles Davidson: This slide is looking at our total TAVR volume since 2018. Obviously, 2020 was a rough year for cardiovascular patients because of COVID lockdown. A lot of cardiovascular programs and many of the beds in the hospital were utilized by COVID-positive patients that we allocated at that point in time. We have seen good growth coming out of the pandemic. This year we're looking to hopefully at least match if not exceed what we've done in the past.

TAVR/Aortic Valve-in-Valve versus Surgical Volume



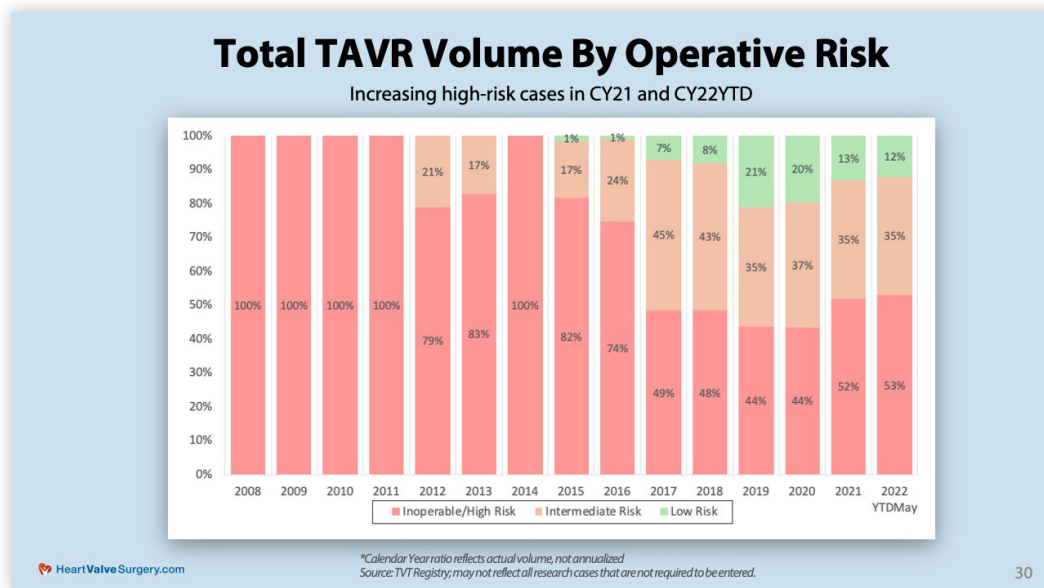
Dr. Charles Davidson: I want to mention on that last slide was that there was a number of research studies going on in this area right now. Valve-in-valve procedures are approved for only patients that are high-risk for a repeat operation. So, we've been really looking at intermediate-type risk patients to try and understand whether this is a good treatment for them as well. Those data are forthcoming. The early results are very promising. I think the importance is going to be what the durability is. As I think Dr. Mehta demonstrated nicely, when you start stacking one valve in under another, you're going to create some degree of stenosis just by the effect of a Russian-doll situation where you're making the effective orifice area smaller even though you're taking the diseased valve out of the equation.

Looking at this slide, a TAVR aortic Valve-in-Valve versus SAVR distribution, I think this is what's really interesting to me. When we started with this back in 2018, you can see aortic valve surgery was 93% of patients with aortic stenosis were requiring another valve. Now, into 2022 and really looking – it's been pretty flat from 2016 on is about 75%, depending on the year, to 80% of patients are able to be treated with transcatheter-based therapies for aortic stenosis. Now, I think the bicuspid population is unique, and many of those patients have aortopathies that also need treatment.

This is not just talk about the aortic regurgitation patients but really aortic stenosis is – three out of four patients now basically get treated with catheter-based therapies rather than open heart surgery. This is important to understand: the age of the patient; what's the lifetime management of their valvular heart disease. It may be very different from a 60-year-old than it is for an 80-year-old because the 60-year-old – likely one biological valve will not be durable enough to get them through their life.

This is where the informed patient and patient decision-making and advising and shared decision-making is critically important.

TAVR Volume by Operative Risk



Dr. Charles Davidson: Back in 2008 to 2011, TAVR was only approved for patients that were high-risk or somewhat inoperable. Many of them were inoperable. As the technology has improved, many now in our fourth generation of some of these technologies, you can see that this has shifted a bit. Interesting enough, the low-risk population seems to be a minority of the group but often owing to that younger patient, maybe do surgery first and then when they need their second procedure, think about an aortic Valve-in-Valve or mitral Valve-in-Valve option.

TAVR Experience

Northwestern Medicine TAVR Experience

- Started TAVR program at Northwestern Memorial Hospital in 2008
 - Expanded to NM Central DuPage Hospital in 2016
 - Also offer TAVR at NM McHenry Hospital and NM Palos Hospital
- Participated in the initial US FDA PARTNER 1,2 and 3 pivotal trials that enrolled high, intermediate and low risk patients in trials for TAVR
- Currently using 4th generation TAVR technology that has improved outcomes
- Over 2,000 transcatheter valve procedures performed at NMH to-date
- Currently FDA approved for all surgical risk including low risk with commercially available TAVR
- Trials ongoing to define long term outcomes of Mitral and Aortic VIV procedures

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Dr. Charles Davidson: So just to give you an overview of the whole Northwestern Medical System, we did our first TAVRs in 2008. We were the first in Chicagoland to do that. We expanded to Central DuPage Hospital in 2016 and their on target, I think, to do over about 150 TAVRs this year. We also offer TAVR at McHenry Hospital and then Palos Hospital. We were in the PARTNER clinical trials. Those were pivotal trials that got approval for the high, intermediate, and low-risk patients. We've now done over 2,000 transcatheter valve procedures.


One of the areas that's really been exciting for us now is working in the tricuspid area where the transcatheter tricuspid valve replacements and repairs and also in the mitral area where needed valves can be treated with either repair or replacement, not really the subject of today's talk but a high-growth area; it'll be interesting to see how that plays out over the next few years as far as what

proportion of patients still receive surgery versus those who receive catheter-based therapies. This is a more complex anatomy. It will take time, I think, to really achieve the type of 75/25 results that we see now, and it may never get quite to that point. I think this is open for discussion. Look, we want to do what's right for the patient and offer a lot of options depending on risk levels and anatomy.


Currently, the FDA has approved for all surgical risks for TAVR. As I said, for Valve-in-Valve, it's for really high-risk and there are trials coming out on the intermediate risk. Really, the long-term outcomes are critically important, whether it be mitral or aortic, tricuspid Valve-in-Valve procedures as we try to unfold this over the next five to ten years.

It's been a pleasure to speak with everybody today about what we're doing and what the field – how the field's moved. I think what I'd like to take away from today is this is one center that does a lot of procedures, but there's many great centers throughout the country that are doing a lot of excellent work as well. This is really intended to be informational for people to help you get informed on how to manage a heart valve disease. Thank you.

Patient Spotlight: Joy Marks

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Patient Spotlight: Joy Marks



- 80 Years Young from Chicago, IL
- Teacher for 30 years
- Enjoys dancing, yoga and walking
- 2014: Mitral Valve Replacement
- 2022: Mitral Valve-in-Valve Procedure

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Adam Pick: We're so thrilled that Joy Marks could join us today. All that we've learned today from Dr. Mehta and Dr. Davidson, you're the living proof. Let's talk, going back to 2014, Joy, you're diagnosed with severe mitral regurgitation. You're told you need open heart surgery. You go through that process. Can you share for the patients what was your experience with open heart surgery? Did you have any challenges or how did it work for you?

Joy Marks: I was very happy with how much progress has been made in open heart surgery. Because in 2014, I had the full treatment. It involves quite a bit of pain with breathing and coughing but I did recover very, very well. I was in recovery for ten days at a facility. I was having a pretty good time.

Adam Pick: Joy, you strike me as the type of person who always is looking for the silver lining in everything. Did you get “back to life” after your first procedure to doing the things you love, like yoga and dancing and all those things?

Joy Marks: Yes, I could do everything.

Adam Pick: Everything, and so for the folks on the line, Joy is 80 years young. She’s been teaching in Chicago for the past 30 years. But then, 2022 comes around and what did you learn from your doctors?

Joy Marks: That first there was a problem, and then with more testing, it was absolutely necessary that that mitral valve be replaced. I was not happy to go through open heart surgery again. One is the fact that you have schedule your life to take enough time to recover, whereas with the new procedure, I took one day off.

Adam Pick: Just one day off. Let’s talk about that, Joy, because it’s a new procedure, right? Did you have any concerns that maybe the transcatheter mitral valve in valve reoperation might not be for you?

Joy Marks: No, I was just delighted that I was a candidate for it. I didn't realize that being old was part of the reason I got to do it, but oh, well, whatever. I never had any worry about it. I just knew that I did not have to go through open heart surgery. One person I know had the procedure at Northwestern Medicine and I very much trusted the doctors. I wasn't concerned at all.

Adam Pick: Let's talk about the Valve-in-Valve procedure, because from the patient perspective – we've heard a lot from the doctors today about the science and the treatment process and all of this fantastic innovation. I'm curious to know from the patient perspective. Can you share what your experience was like getting a mitral valve replacement reoperation?

Joy Marks: I came into the hospital the day of the procedure. I had to wait a little while because there was a person ahead of me. I had no discomfort at all. I was, of course, fully anesthetized. I think the reason I'm here is that the second I woke up, I heard a doctor saying, "That went great," and I guess it did. I did need to go into intensive care for it to be monitored but I really didn't need – I think I could've just walked home.

Adam Pick: How long were you in the hospital for?

Joy Marks: I was the hospital for two nights. I was there the night of the procedure and then just to check on me I guess I stayed one more night.

Adam Pick: Now let's talk about your life after the procedure. You said you were going to walk home. That's a pretty good indicator that things went really well. How are you doing now?

Joy Mark: Really well. I hoped to have some change in my life quality right away but that didn't happen. It took about four weeks before I started noticing that I was stronger, that I was more resilient, that I was more involved with things. I think all who are listening, this heart problem usually goes slowly. I did not realize that I was regurgitating for a while so I didn't know I needed to get better. Then, when I did get better, I thought this is really nice. This is great. I'm able to do all of the things I want to do now.

Adam Pick: How active you are as an 80-year-old. I'm going to ask you some yes and no questions. Are you still teaching?

Joy Marks: Yes.

Adam Pick: Are you dancing these days?

Joy Marks: Yes.

Adam Pick: Are you going on walks?

Joy Marks: Oh, every day.

Adam Pick: Do you do any form of exercise?


Joy Marks: Yes, I live as an independent person in a senior residence and they offer a lot of activity. I take a yoga class twice a week and I take a regular exercise class twice a week and a lot of other stuff.

Adam Pick: I just want to take another second, Joy, to thank you. I've got probably a big question that might come up at the end, but why don't we answer it right now? What advice would you have for patients if they need a heart valve reoperation?

Joy Marks: The first thing is to address it right away. Everyone knows that every two years you should have a sonogram. I had sort of forgotten about it. It was two and a half years before this was detected. Don't do that. Keep up with your testing so you know that you're at the best you can be, and then don't waste any time before you get it corrected.


Adam Pick: Great advice, Joy. I was like you. I skipped two years of getting my echocardiogram and my valve stenosis went from moderate to severe and then I was in a panic over what to do. Thanks for being with us, Joy.

Questions & Answers

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Valve Size

Joni asks, "How big does the valve have to be for the 'Valve-in-Valve" procedure have to be? I was told that this prominent my surgeon put too small of a cow valve inside of me for my mitral valve. I need a 'Re-Do' at some point which would be open heart #4."



27mm

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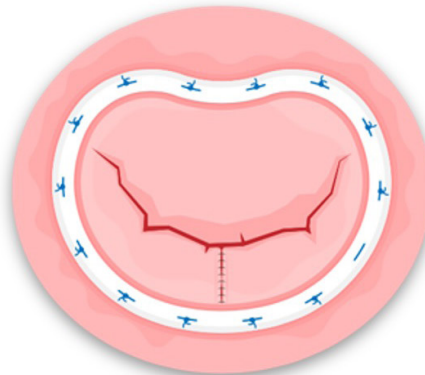
Adam Pick: We're going to start the "Questions & Answers" section of the webinar. This is a great question from Joni who asks, "How big does the valve have to be for the valve in valve procedure? I was told by this prominent surgeon that there was too small of a cow valve inside of me for my mitral valve. I need a redo at some point which would be open heart Number 4."

Dr. Christopher Mehta: Let me address that one. It depends where we're talking. For the aortic valve, everybody's anatomy is a little bit different. Some people actually have a small annulus where the valve sits. We size at the time of surgery to see what would be the best size. Now, in the era of transcatheter with understanding that we may need to do Valve-in-Valve procedures in the future, I think surgeons in general are much more cognizant about putting large enough valves in such that in the future, if somebody needs a Valve-in-Valve within that bioprosthetic valve, that we could safely do that.

Something that we do that's becoming much more common these days is an aortic root enlargement, which means that if the annulus is too small and we are concerned the valve may be too small, we can actually expand that annulus to some degree in order to accommodate a larger sized valve. Now, in the mitral position, we don't really have the enlargement option, but again, it's the same thing. We're very cognizant about making sure we can put in a large enough sized valve in there. This is one of the things that we consider when we do this heart valve team multidisciplinary meeting is we look at the size of the valve and that may determine one way or the other whether somebody is a suitable transcatheter Valve-in-Valve candidate.

Dr. Charles Davidson: To put it succinctly, the larger the valve that's in there, the larger valve we can put in, and then the better the flow is. We also know that the chances of that valve lasting a longer period of time is better if it's a larger valve than a smaller valve. This is, again, not a simple question, but one that's also worth discussing with your cardiac surgeon and cardiologist because you may be able to do it, but the longevity may not be good if it's small, or if it's large it may be much, much better.

Marie asks, "I had a mitral valve repair 15 years ago but it's starting to leak again. What are my options if I want to avoid another open-heart surgery?"




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Adam Pick: Next question coming in from Marie, who asks, "I had a mitral valve repair 15 years ago, but it's starting to leak again. What are my options if I want to avoid another open heart surgery?"

Dr. Charles Davidson: Well, we didn't talk, really, about Valve-in-Ring procedures, which is what this is describing because most of the repairs are done with a ring that's left in place. There are various types of rings which some are more amenable to a Valve-in-Ring procedure than others. We often need to do a fair amount of testing, which will include a CAT scan, echocardiography, and it will be shared decision-making with these patients. This is an area that also is only approved for high-risk. Certain rings are very good for it, and it may be an option for you. A lot more we'd have to know in order to understand whether you're a good candidate and whether this could be offered to you.

Dr. Mehta, as a cardiac surgeon, obviously understands this very well, what surgical options may be available and Dr. Mehta and I obviously do Valve-in-Ring procedures together as well.

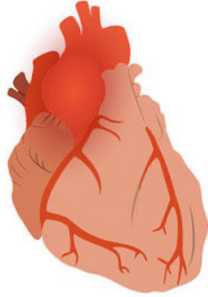
Dr. Christopher Mehta: To echo a point that Dr. Davidson made, these rings that are used in mitral repairs do come in all different varieties some are rigid some are more flexible some are complete rings some are partial bands. That's part of what we do in the multi-disciplinary meeting is assess what type of ring it is and would that be amenable to a transcatheter procedure and as a surgeon you know we have insights into those options.

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Aortic Aneurysm

Sheldon asks, "My cow valve in the aortic position is starting to fail and I now have an aneurysm. Is there any transcatheter way to fix both problems without opening me up?"

Ascending aortic aneurysm

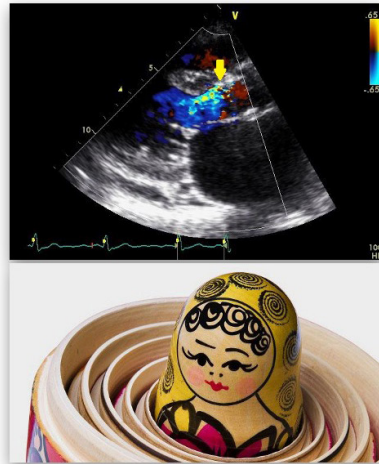


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Adam Pick: Sheldon asks, "My cow valve in the aortic position is starting to fail and I now have an aneurysm. Is there any way transcatheter methods can fix both problems without opening me up?"

Dr. Christopher Mehta: Right, so right now there is no good endovascular or transcatheter option to address aneurysms. The reason aneurysms are a concern is because if they get big enough, they can lead to aortic dissection or aortic rupture, which are both life threatening and potentially fatal problems to have. When we see patients who have an aneurysm and a previous valve that needs to be addressed, those folks tend to need surgery.

Eli asks asks, I am 94 and four years ago I had a TAVR that has worked well even with slight paravalvular regurgitation. Please comment re likelihood of a successful transcatheter aortic valve-in-valve procedure if my present valve fails. Thank you."



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Adam Pick: Eli asks, "I'm 94. Four years ago, I had a TAVR that has worked well, even with slight perivalvular regurgitation. Please comment regarding the likelihood of a successful transcatheter aortic Valve-in-Valve procedure if my present valve fails."

Dr. Charles Davidson: Dr. Mehta kind of covered this. I'll maybe pick up on what he already said. I like the Russian doll analogy. I use that when I'm talking to patients in clinic. First of all, a Valve-in-Valve and a valve in TAVR, TAVR in TAVR is what we usually call it, is something that we do and can be done. Since TAVR has not been around as long, there's not been a ton of experience with it, but once again, a lot of it depends on how large the valve is that's in there already. The larger the valve, the better chance we get a great result with the second valve.

For example, the SAPIEN comes in 20, 23, 26, and 29 millimeters. For example, if you've got a 29 in there, it would be great about putting a second one in. If you have a 20 in there, it is going to restrict flow to some degree in longevity of that valve as well as initial flow is not going to be quite as good. It is an option and something you could probably find out more about right now if you just knew what valve size you have in there already. There are some other aspects of this, too, that have to do with coronary heights and the likes, but I won't get into that much detail at this point.

Adam Pick: Great, for everybody on the line, thanks so much for being here. We're coming to the end of the hour, but please don't hang up just yet. We want to thank you all the members of the HeartValveSurgery.com for being a part of this community event. It is fantastic to get on the line and learn with you about things like the advances in heart valve reoperations. We want to thank Dr. Davidson and Dr. Mehta for taking time away from their very busy practices at Northwestern Medicine. Yes, we have to thank Joy for being our patient spotlight on this webinar. Joy, you're definitely inspiration to so many people out there on this call who have not just one but two heart valve procedures and are still having a great time in their life enjoying yoga, dancing, exercise, and walking. Thanks to all of you for being with us today.

HeartValveSurgery.com Resources for Patients

Since 2006, HeartValveSurgery.com 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 dis-ease and treatment options for aortic, mitral, pulmonary and tricuspid valves.
- [Heart Valve Learning Center](#) - Visit the Heart Valve Learning Center to access over 1,000 pages of educational information about valvular disorders.
- [Patient Community](#) - 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.
- [Surgeon Finder](#) - Find and research patient-recommended heart surgeons that specialize in heart valve repair and heart valve replacement procedures.
- [Heart Hospitals](#) - 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.
- [Educational Videos](#) - Watch over 100 educational videos filmed by the Heart-ValveSurgery.com film crew about heart valve surgery.