

## Transcatheter Aortic Valve Implantation

Webcast

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Rose Spagnola

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### **Rose's Story**

#### **Andrew Schorr:**

Aortic stenosis, though uncommon, is a serious health issue. It must be monitored closely by your healthcare provider. Fortunately, there are new investigational procedures that are changing the way the condition is treated. Coming up you'll hear from a leading cardiologist from Northwestern Memorial Hospital in Chicago as he discusses transcatheter aortic valve implantation or TAVI. You'll also meet a woman who benefitted from it. She says it gave her back her life.

Hello and welcome to Patient Power sponsored by Northwestern Memorial Hospital. I'm Andrew Schorr. Well, certainly if your heart is not doing well, that can very much affect your life. We're not just talking about heart attack, something acute like that, but we're often talking about when the heart muscle just is not doing its job and it gets harder and harder and harder for you to have a quality of life, even get out of bed, and unfortunately as we age that can happen.

What can you do about it? Well, there can be medications, and sometimes those can help. And certainly for many years there's been open heart surgery, but that's not right for everybody, and, let's face it, some people as they get older they may not be candidates. It could be a high risk. Well, medical science marches forward, and now there is very promising results from a new procedure called transcatheter aortic valve implantation. The acronym is TAVI, and I'd like you to meet somebody who has benefitted greatly from it. We're going to go to Homer Glen Illinois, about an hour south of Chicago, Rose Spagnola joins us.

Rose, how old are you, 80-what?

#### **Rose:**

86.

#### **Andrew Schorr:**

Okay. Let's go back to just a little more than a year ago. How were you doing? What was life like?

#### **Rose:**

I was not doing well. I was using oxygen just about all day, and I had to sleep with it at night. I was in and out of the hospital, and the last time I was in the hospital after we moved to Homer Glen I was told that maybe I had a year to live.

**Andrew Schorr:**

Oh, my. Now, you've been married 64 years to Matt.

**Rose:**

Right.

**Andrew Schorr:**

He had his own heart problems, I know, years ago, with a quadruple bypass.

**Rose:**

Right.

**Andrew Schorr:**

But he's been doing okay.

**Rose:**

He's doing fine.

**Andrew Schorr:**

So here you are, a husband who is doing well, overcame his heart problems, but yours were getting worse, and there were some doctors who said they couldn't do anything more for you.

**Rose:**

That's right.

**Andrew Schorr:**

Oh, man, that's terrible. And you've got your three kids and grandchildren and how many great-grandchildren?

**Rose:**

Six.

**Andrew Schorr:**

And you couldn't enjoy them.

**Rose:**

No.

**Andrew Schorr:**

Oh, my. All right. So fortunately somebody said maybe the cardiologists at Northwestern could help.

**Rose:**

Yes, that's right.

**Andrew Schorr:**

So in January of 2010 you had a procedure. Tell us about that. You went into the hospital, they put you to sleep, what happened?

**Rose:**

They put me to sleep. I woke up in ICU and in 24 hours I was out of ICU. I stayed in the hospital after ICU for five days and I came home. And the minute I walked into the door here, we have a receptionist, and she said oh, my god, Rose, you look like a different person.

**Andrew Schorr:**

And they saw your color had come back in your cheeks.

**Rose:**

Yes.

**Andrew Schorr:**

You were a new person. So how do you feel about this? You had this TAVI procedure. When you think about it and how really maybe weren't long for this world, am I right that you feel it gave you your life back?

**Rose:**

Yes, it gave me my life back. I'm able to do things. If I want to go someplace I'm able to do it. Of course I'm 86 years old, I can't do everything I did 30 years ago, but I can basically do everything I could do before.

**Andrew Schorr:**

Tell us about some of the activities. So you can play with those great-grandkids, right? And you can go to church, and...

**Rose:**

Yes, we can play. They come to visit in our apartment here, and we enjoy them and we can play games with them. And I can fix breakfast and lunch. I don't have to fix dinner because where we live we have a big dining room and we have dinner made for us every night. And I enjoy going shopping and just having company and visiting with everybody, where before I would have to go lay down because even visiting would tire me.

**Andrew Schorr:**

All right. Well, as you know, a physician who played a key role in this, your doctor is Dr. Charles Davidson who is with us today as well.

**Rose:**

Yes.

**Andrew Schorr:**

Dr. Davidson is an interventional cardiologist at Northwestern Memorial Hospital in the Bluhm Cardiovascular Institute. He's also the medical director of the Bluhm

Cardiovascular Institute, and he has been participating in a clinical trial where they've been seeing whether this TAVI procedure can help many people. Now I know a *New England Journal of Medicine* article came out, and, Dr. Davidson, we hear it as a specific example with Rose, but this procedure has been helping many, many people who otherwise couldn't have surgery. Am I right?

**Dr. Davidson:**

Yes, it has. It actually has really changed the course for these patients who we know had a very poor prognosis with medical therapy, and as you pointed out earlier, really didn't have good surgical options. And the *New England Journal* article, which was published just a couple months ago demonstrated a 30 percent improvement in survival at one year, which is really dramatic when you think about it. We've had nothing in cardiovascular disease either by therapeutic treatments with catheters or with medications that's generated a 30 percent absolute reduction in death at one year with this treatment.

**What is Aortic Stenosis?**

**Andrew Schorr:**

All right. Let's get a little specific now. So first of all what was going on with Rose's heart that was making it where she needed oxygen, she got tired, she couldn't do activities? What was happening there? I use this term "aortic stenosis," was that it, and what does that mean?

**Dr. Davidson:**

Rose actually had two problems. She had a blocked artery and she severe aortic stenosis. Initially we treated her blocked artery, but we knew that the primary problem that needed to be repaired was this valve in her heart called the aortic valve. This is the main valve leading out of the heart that allows blood to circulate throughout the body, to the brain, to the other organs of the body. So over time calcium can build up in this valve and impair the ability of that valve to open, and therefore blood tends to back up into the lungs and causes shortness of breath and fatigue, and all the symptoms that Rose described are kind of classic for this problem.

It's not really related to diet over time or anything. It's just that as you age calcium can build in this valve and the valve no longer opens properly and severe aortic stenosis develops. And it is very common in people in their 70, 80s and 90s for this to be a presenting problem in patients with heart failure.

**Andrew Schorr:**

So before the TAVI procedure there were other options, and you mentioned medical therapy, so does that mean some sort of medicine or medicines that maybe could try to help the valve work better?

**Dr. Davidson:**

So the medications really work on improving the amount of fluid that is in the body

so to kind of help the body remove the fluid, but it really doesn't change the outcome of the disease. This is different from coronary artery disease where medications can really prolong survival and prolong the time to heart attack. This is a mechanical problem, and really the only way to treat this and avoid the grave consequences of it has either been by open heart aortic valve replacement or now this new procedure of a transcatheter aortic valve implantation.

The medications are really ineffective and they're just treating the secondary phenomena, and unfortunately people's death rate at one year when they develop the severe symptoms like Rose had is about 50 percent die in the first year.

**Andrew Schorr:**

Oh, my. Now let's talk about the way it had been done traditionally with surgery. What would be involved there, and who would be judged to be at high risk where it wasn't really a reasonable option?

**Dr. Davidson:**

So traditionally this is done by open heart surgery which generally involves opening the chest through the sternum and replacing the valve. And that always has been an excellent way to treat patients with aortic valve stenosis. And in a person without any other risk factors this would still be considered to be the best way to treat these patients.

However, in Rose's situation and in a multitude of patients because of advanced age or because of other medical problems, let's say, a poorly functioning heart that is a weak or they have had a previous stroke or maybe they've had previous open heart surgery so the risk of traditional aortic valve replacement becomes high in those patients, and that's where this procedure is indicated it at this point in time is for people that are at high risk for traditional aortic valve replacement.

**What is TAVI?**

**Andrew Schorr:**

All right. Let's understand what TAVI means. I had said transcatheter aortic valve implantation. So help break that down. What does it mean for someone like Rose when they come to the hospital? How do you do it?

**Dr. Davidson:**

So this is a procedure that can be done one of two ways. It's a valve that's actually mounted on a catheter, and a balloon is inflated to insert this valve inside of the person's native valve. So the native valve remains in place, it's just pushed out of the way, and this becomes the functioning valve. It's a cow valve that's mounted on a metallic stent that again with a balloon is inflated over the old valve and this becomes a new functioning valve.

The two ways it can be placed, one is through an artery in the leg where we navigate up through the aorta across the old valve and then inflate the new valve in

place. And the other way it can be done is through a small incision between the ribs, about a two-inch incision between the ribs where we go directly into the apex of the heart and then inflate the valve that way. That technique is reserved for people whose leg arteries are too small to accommodate the valve being placed up through the leg artery.

**Andrew Schorr:**

All right. Let me go over this again. I think some people are familiar with angioplasty or even angiograms, but where you go up through the groin and you're either with an angiogram looking to see what's going on with the coronary arteries or I know you can go in and do balloon angioplasty or put stents in to try and open up the coronary arteries. I understand this is different, but you're going in, let's say, from the groin, would be the prime way, use the balloon as you would otherwise, but then you have this sort of attachment to it of something you're leaving there, right?

**Dr. Davidson:**

Right. So this is somewhat of an extension of an angioplasty. It's a larger catheter because you're carrying a valve instead of just a stent, so this is a stent and a valve inside of it. And it's again migrated up through the leg artery, and we cross over the native aortic valve and then implant this valve in there. So people that have had angioplasty or angiograms would be familiar with this type of diagnostic and therapeutic type of treatment. The main difference is it's a much larger device than what we use for the arteries, and this is specifically to treat a valve problem, not an artery problem.

**Andrew Schorr:**

And you do it in the catheterization lab?

**Dr. Davidson:**

Right. This can be done in the cardiac catheterization laboratory or sometimes we do it in our hybrid operating room suites, and it's done in both areas which are very similarly equipped for x-ray imaging, because all of this is done under x-ray guidance. And currently we do it under general anesthesia, and we use echocardiograms to also guide the placement of the new valve into place. So it's done by both x-ray and ultrasound guidance.

**Andrew Schorr:**

And, Rose, you were put to sleep and you don't remember any of it.

**Rose:**

I don't remember a thing.

**Andrew Schorr:**

Okay.

**Rose:**

I woke up and I remember I was thirsty.

**Andrew Schorr:**

Okay. And when you woke up did you need oxygen?

**Rose:**

No.

**Andrew Schorr:**

All right. That was a big deal. Dr. Davidson, so you open this up, and we're talking about this is the blood flowing out of the heart through the major artery, the aorta, to supply oxygenated blood or blood that pumps all around the body. So once you do that, someone like Rose, do they get--I know there's a recovery time, but she saw an immediate difference.

**Dr. Davidson:**

Most people will feel an immediate difference because you've really relieved the obstruction to flow outside of the heart. Of course, everyone has a different recovery time from any procedure, and although this is much less invasive than open heart surgery it still is a major procedure and everyone has a little different time to recovery. But in people that have a successful implant they generally feel the relief virtually instantaneously.

**Recovery**

**Andrew Schorr:**

Wow. Now, a little more about the recovery. So what is the way you do it now at Northwestern? How long is somebody in intensive care and then in the hospital typically if everything goes well? And then what is the recovery like?

**Dr. Davidson:**

So everyone is a bit variable because we're taking patients that are very high risk for traditional aortic valve replacement. Typically, patients' recovery is going to be a little bit longer than a patient that doesn't have other medical problems. But the standard would be to spend about a day or two in the intensive care unit and about three to four days as an inpatient just getting their strength back, but that varies from patient to patient and is often limited by other comorbid problems as we described earlier. They might have poor heart muscle function, poor lungs, poor kidney function, prior artery disease in the neck arteries, and all of those things can affect the recovery time for our patients.

**Andrew Schorr:**

Rose, how about you? So when you got home, maybe you needed a little help. You looked better, you said the receptionist at the senior center where you live, they immediately saw a difference. How long did it take you to feel like your old self?

**Rose:**

I would say that maybe around nine months I started to feel like I was really able to do a lot of things. In the beginning I did take a nap every afternoon and I would get up refreshed, but as time went on I don't need a nap in the afternoon. I can sit and do whatever I want or go for a walk, you know.

**Andrew Schorr:**

And you gave up oxygen immediately.

**Rose:**

Oh, yes. Yes. I was never so glad to sleep without oxygen.

**Andrew Schorr:**

Right. I'm sure that was a big deal.

**Rose:**

Yes.

**Risks of the Procedure****Andrew Schorr:**

Dr. Davidson, so what are the risks? We're talking about often older people, and you talked about how they may have something else going to know too, so any medical procedure has its risks. What do we know about TAVI now?

**Dr. Davidson:**

So there were some nice data presented in the *New England Journal* article that was published a couple months ago that we spoke about already, and I think the major risk that people concern themselves with is the risk of stroke and the risk of serious bleeding problems from the catheter because they are larger catheters. And this is where I think as the technology improves we'll make strides in both of these areas.

The catheters that we're going to be using actually within the next month are smaller catheters, considerably smaller than what we're using already, which we hope will actually have an impact on both bleeding complications and the incidence of stroke from the procedure. The stroke occurs primarily from the placement of the new valve over the old valve and probably some calcium breaks loose from the valve, and we're hoping with a lower profile system, a smaller system, that this will also be reduced.

**Andrew Schorr:**

Now, of course anybody going through a procedure has to go in with their eyes open about the risks, but I know Rose would agree, but otherwise folks, Rose, you were kind of out of options, right? I mean, you went in knowing there were risks.

**Rose:**

Yes.

**Andrew Schorr:**

But they had told you you might only live a few months.

**Rose:**

Yes. They actually gave me a year maybe, yes.

**How to Be a Part of the Clinical Trial**

**Andrew Schorr:**

Right. Right. So you needed to go forward. So, Doctor, we talked about this being an investigational or has been in a clinical trial basically. Help us understand, is this available now to people who come to Northwestern or one of the other leading centers where this has been studied?

**Dr. Davidson:**

So it's available in about 25 centers around the country right now. We've been implanting these for a little over two years. What's nice about the trial as it's currently being done is that patients who qualify can be guaranteed that they will receive the valve. Previously there was a randomized part of the trial which means that half the people would get the new valve and half would still go for traditional surgery or would be offered just traditional medical therapy. But as it's currently configured any patient that actually qualifies would be able to get the valve. And in order to qualify primarily you have to be high risk for the traditional aortic valve replacement.

**Andrew Schorr:**

Now, how does someone, if someone is hearing this and they hadn't heard about it, let's say, quite frankly with their local cardiologist or they were told, well, it's experimental, I don't know, etc., but if they want to inquire further can they self-refer and come see you at the Bluhm Cardiovascular Institute? Do they need a referral? How does it work?

**Dr. Davidson:**

Many of the patients we've done have been self-referred and many have been referred from other physicians, but we are happy to evaluate any patient that believes that they have aortic stenosis and would like to explore other options besides regular aortic valve replacement. They can contact us at the Bluhm Cardiovascular Institute and we'll be happy to evaluate them. We actually have a specific clinic there called our valve clinic where our cardiac surgeons and cardiologists see the patients on the same day and are able to review all of their records and try to give you an opinion as to what would be the best treatment, whether it be medicine, whether it be aortic valve replacement or whether it be the transcatheter aortic valve implantation.

**Andrew Schorr:**

Rose, you and I spoke about this on the phone the other day. Do you feel that you are just blessed, if you will, that the critical procedure that you needed that could make a difference became available when really it was a special time for you where you had to have something like that?

**Rose:**

Yes. I was really, really glad that they approved, and I went into surgery without any fear. I just felt that it was the thing for me to do.

**Andrew Schorr:**

Yeah, I know it made a huge difference. So, Doctor, would you call it a breakthrough in cardiology? But it sound like a big deal because here are older patients like Rose, they were maybe out of options and now it seems like you're getting terrific results.

**Dr. Davidson:**

I look at this as the biggest development in interventional cardiology and cardiology since the advent of stents. You look at somebody like Rose and she's absolutely a huge success story. This is a lady that would have had really no options. Her survival at one year was probably 50 percent or less. We've given her more years of life and we've given her higher quality of life, and I think that's really what we're aiming to do here is improve quality of life and improve longevity. And this is a treatment that really appears to do both.

**Symptoms of Aortic Stenosis**

**Andrew Schorr:**

Now, we mentioned that aortic stenosis is not common. So how do people develop it in the first place? Rose, you've told me that you were living with a heart murmur. Does that come into play, or what are the causes, Doctor?

**Dr. Davidson:**

So typically people have a valve that maybe wasn't completely normal at birth but really doesn't cause a problem throughout their life, but as time goes on because the flow through that valve wasn't completely normal, calcium builds up in that valve. And it's not from dietary indiscretion or lack of exercise or anything that you can say that maybe could have done differently. It's just the calcium flow and blood flowing through that valve over the years has caused some calcium to be deposited there. And once the calcium gets deposited it restricts the opening of the valve. And once it's been restricted to a severe degree then that blood begins to start backing up causing symptoms of heart failure, shortness of breath or passing out spells or it can cause chest discomfort or angina-type symptoms. Those are the cardinal three symptoms of severe aortic stenosis.

**Andrew Schorr:**

Now, you mentioned that you're going to move to a smaller catheter, so it sounds like it continues to be refined.

**Dr. Davidson:**

Right. This is a procedure that's really in its infancy right now. And this is first-generation technology that we're using on our patients right now, but we know that catheter size will decrease. We know that protection devices will become available to prevent any plaque embolization to the brain that will affect the stroke rate. So I believe in three, four, five years we will be looking at this in a different way than we do right now, but even as it's constructed right now and how it's done right now it seems to be a major breakthrough in improving survivability and quality of life.

**Andrew Schorr:**

Dr. Davidson, there are other valves in the heart as well. Is this the leading edge, if you will, where there will be other valve repairs that can be done in a minimally invasive way?

**Dr. Davidson:**

Absolutely. There is already work being done with other valves in the heart. In fact one was recently approved for the pulmonic valve. That's typically more of a problem in the pediatric age group, and that was just approved. And people are looking at replacement of mitral valves in this way as well. So over the next five to 10 years you'll see a big evolution in the way that we treat other types of valvular disease, but the aortic one was kind of the first one to attack and actually the most prevalent one among patients with valvular heart disease.

**Diagnostic Testing****Andrew Schorr:**

Wow. Well, it's certainly good news. I want to just understand. If somebody listening says, well, I have those symptoms that you described, when someone comes to your institution what diagnostic tests are you going to do to then determine whether TAVI, whether it might be right for them?

**Dr. Davidson:**

So most people will have had some evaluation beforehand, but if they haven't we would want to do an echocardiogram to evaluate how severely blocked the valve is and how well the heart muscle is functioning. If that looks like it is severely blocked then the additional tests that we would do would be to do a CAT scan to evaluate the arteries in a person's body to see if they're big enough to accommodate this catheter. We also do tests of pulmonary function. We'll do a blood test for kidney function. We do some ultrasound of the neck arteries to look and see if there are any blockages in there as well. So there are fairly straightforward, noninvasive tests that are needed.

And then the one invasive test that's needed is they need a coronary angiogram to see how the coronary arteries are, which as I pointed out earlier in Rose's case she had a blocked artery that we needed to repair first with a stent before we would

implant the valve. But that's really the only invasive test that needs to be done to kind of evaluate of entire evasion.

## **The Future**

### **Andrew Schorr:**

And what about follow-up? So here Rose is doing well, and you give them their life back. How do they have to be monitored? And you mention that it's a cow valve that's been put in there. How lasting is that? Now, obviously people may be in advanced years but what about the durability of this?

### **Dr. Davidson:**

That's a good question. The cow valves seem to be the most durable, and those are the ones that are used when traditional aortic valve implants are done. In fact the one we're using is very similar to the one that is used by this manufacturer for their traditional aortic valve replacements. We generally monitor these by doing echocardiograms at six months and one year and then annually afterwards to look at the function of the valve.

The best data we have thus far on durability comes out of Europe where over 20,000 of these valves have been implanted to date because it is an improved procedure in Europe. And the data is about out to approximately six years now, and it seems to have excellent durability, but I think this is something we'll need to investigate and watch further on what the 10- and 15-year durability is of this.

One of the exciting pieces about this is if let's say 15 years we are running into durability issues is you can implant another valve inside of this valve. So even if it did have some problems with that there may be options short of surgery to perform a second procedure. Obviously we're hoping that the durability is going to be just outstanding and that won't be the question, but it's something we'll need to continue to investigate.

### **Andrew Schorr:**

Wow, Rose, it sounds like if I do the math, if this is durable or you needed another valve put in you could live to 120 with your heart.

### **Rose:**

Well, gee, whiz, I could be a great-great grandmother.

### **Andrew Schorr:**

That's right. Rose, is there anything you want to say to Dr. Davidson publicly for the work he and his team did for you?

### **Rose:**

I want to thank him very, very much, and I want to tell him that I pray for him every day for the work that he's doing.

**Andrew Schorr:**

And you send him those wonderful cookies at Christmas time.

**Rose:**

Well, since he liked them so much he might be surprised and have another package arrive.

**Andrew Schorr:**

Another shipment, okay. Rose, you know, some people are told as you were first up in Wisconsin where you had retired to and also, well, we can't do anything more for you. And you with the help of another physician as well kind of went the extra mile and that connected you with Dr. Davidson.

**Rose:**

Right.

**Andrew Schorr:**

And the team at Northwestern. What would you say to people listening? Maybe they tune in on the internet or their adult children do, and they've been told where they live that there wasn't much else to do? What would you say to them?

**Rose:**

I would say to them, find a hospital that does it. And I was told in Wisconsin too that my best chance would be to go to Northwestern.

**Andrew Schorr:**

Well, you got some good advice. Dr. Davidson, you must feel great about the technology and the skill of your team that's come together with this and the development that continues and just hearing Rose's story too and feeling to be part of it.

**Dr. Davidson:**

You know, this is why you go into medicine and why you go into cardiology is to hopefully be able to treat people like Rose and to really improve their life and give their family a longer time to be with her and her longer time to be with her family. And this is one of the most rewarding pieces of really being a physician is to be able to treat people like her and get her well.

**Andrew Schorr:**

Amen. And watch your mail. You're going to get some of those great cookies coming your way. Okay. Well, this is what we do on Patient Power, and this is just a wonderful story of medical progress that makes a difference to people. Rose Spagnola, all the best to you and your husband of 64 years.

**Rose:**

Thank you.

**Andrew Schorr:**

Matt and those kids and grandkids and great-grandkids. And keep walking, keep breathing, keep active.

**Rose:**

Oh, yes.

**Andrew Schorr:**

And we hope we can revisit with you sometime.

**Rose:**

Any time.

**Andrew Schorr:**

Thank you. And, Dr. Charles Davidson, from the Bluhm Cardiovascular Institute, thank you for being part of research and development and making a difference there for folks like Rose. Thank you, sir.

**Rose:**

Thank you, Dr. Davidson, and God bless you.

**Dr. Davidson:**

Thank you, Rose. God bless you, as well.

**Andrew Schorr:**

Thank you for being with us on Patient Power. I'm Andrew Schorr. Remember, knowledge can be the best medicine of all.

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