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Developments in Surgical Therapies for Valve Disease

### DEVELOPMENTS IN SURGICAL THERAPIES FOR VALVULAR DISEASE.

You are listening to ReachMD, the Channel for Medical Professionals. Welcome to Heart Matters, where leading cardiology experts explore the latest trends, technologies, and clinical developments in cardiology practice.

Your host for Heart Matters is Dr. Janet S. Wright, Senior Vice President for Science and Quality for American College of Cardiology.

Artificial heart valves have steadily evolved since their arrival on the surgical scene in 1960s. A range of the newest devices have shown significant potential including the eventual prospect of valve replacement in high-risk symptomatic patients with severe aortic stenosis. What are the most promising devices on the horizon today? Our guest is Dr. Arvind Agnihotri, Assistant Professor of Surgery at Harvard Medical School and the Director of Cardiac Quality Assessment and Improvement for the Partners Health Care System in Boston.

**DR. JANET S. WRIGHT:**

Welcome Dr. Agnihotri.

**DR. ARVIND AGNIHOTRI:**

Thank you for having me, good to be here.

**DR. JANET S. WRIGHT:**

I am so interested in today's topic. We are going to talk about not just valves that are artificial and available to be replaced by surgery, but some of the newer device options. I am going to ask you a 2 part just to get started; the first is to talk about those options and then if you would walk us through the decisions that need to be made around the choice of those devices?

**DR. ARVIND AGNIHOTRI:**

Sure. I think the first thing to remember when we talk about valve surgery is what a great success it has been. It was not really that long

ago in the 1960s that it was a revolution that we could open the heart, take out a diseased valve and replace it and so we have a lot of data on natural history for these diseases. Before that where we really didn't have good therapy. So, the first thing to remember is we have really done well up-to-date in terms of being able to attack diseased valves and I think we are going to talk predominantly about the aortic valve today and aortic stenosis. We are at now on our third generation of valve substitute meaning that they have progressively improved over time, so that the longevity of the tissue valves seems to be improved. For most patients with symptomatic aortic stenosis, the current surgical therapy is a wonderful success story. Overall, in the United States the mortality an aortic valve replacement is in the 2% range, meaning 98 times out of 100 people with aortic stenosis can get an aortic valve replacement and do well for a very long time. So, I want to sort of start our conversation by talking about our success and then we could talk about how we think we can even extend upon previous gains and may be make this available to more people and may be reduce the morbidity if not mortality associated with it.

**DR. JANET S. WRIGHT:**

But, you know 1 point I wonder if you would comment on that 2% mortality is actually in a population of people at an advanced stage in their lives, correct?

**DR. ARVIND AGNIHOTRI:**

That's correct.

**DR. JANET S. WRIGHT:**

By that we mean that people coming to aortic valve replacement for calcific aortic stenosis are often in their 80s, correct?

**DR. ARVIND AGNIHOTRI:**

80s would be a little bit older. I think that the average age of people we are seeing for aortic stenosis is less than 80. We are seeing people in their 70s predominantly, but certainly we don't consider age in and itself to be a contraindication to valve surgery. I am looking right now at sort of the STS, which is our surgical society database information and we find that about 2 out of 3 people are over 65. So, there is about of a third of patients less than 65, 2/3rd over majority in their 70s. We have not considered age in and itself to be a contraindication for people to have this operation more commonly. Its other organ comorbidities that would make us cautious about proceeding.

**DR. JANET S. WRIGHT:**

I think you are going to tell us more about additional forms of valve replacement or what we are moving into the now, the percutaneous valve replacements?

**DR. ARVIND AGNIHOTRI:**

Sure. Despite the successes we have had, as you mentioned calcific aortic stenosis is a disease that predominantly occurs in the elderly. There are really 2 populations of patients that we see, the minority population are those with bicuspid aortic valves who develop early problems with their valves and some of those patients we see relatively young in their middle ages, the majority of patients with

tricuspid, the normal tricuspid valve who present with calcific aortic stenosis are older over 65, 70, 80, sometimes in their 90s. What we are finding is that despite our excellent results from surgery, there are a lot of patients who are either not referred for surgery because they are thought to be too frail or have significant comorbidities. In a couple of studies that were done in the last several years, the incidence of patients with aortic stenosis who were left untreated was somewhere between 30% and 60%. So there is a population of people out there who have symptomatic aortic stenosis. We haven't talked a lot about the symptoms and the impact of that disease, but we know that it does have an effect on longevity and it can decrease the quality of life and so there is somewhere between 1/3 and 2/3 of people in this elderly population who are not sent for treatment. So we are looking at that population and trying to figure out how we can take care of them without doing a relatively large operation and this new class of devices that we are going to talk about today have been an effort to address this underserved population. The basic idea of doing a percutaneous and I put that word in quotes because percutaneous meaning through the skin, but most of these are done through very small incisions over arteries in the body valve, came out from work that was done initially in Europe. The idea was that using a stent material similar to a stent that we might put in a large blood vessel or even similar in concept to the stents that we put in the coronary arteries. Using this kind of a stent, we could put a valve within it that was collapsed down as a stent was crimped. So this very narrow tube with a crimped stent could be put over a valve and then deployed. In most cases that means that we would blow a balloon up inside this stent and literally the stent material, the radial side would increase inside of the diseased valve pressing the valve toward the wall of the aorta and the valve that was crimped inside of it would unfurl and begin to function. This concept obviously was met with some caution. The surgeons who had looked at these diseased valves for a long time wondered how you could push this bulky calcific valve to the outside and have enough of a functioning valve inside, but a few people really believed in this idea and pushed it forward and in a few very high-risk cases in Europe, they showed promising results. The technology has improved and now I think that almost everyone who looks at this recognizes that this is going to be a really important part of the armamentarium in terms of treating patients. So, just to sort of put this together, what we are saying is that traditional aortic valve surgery, which involves opening the aorta, cutting out the aortic valve, sewing in a new valve and closing the aorta requires the use of heart lung bypass and generally requires making the heart still. This type of surgery does not involve stopping the heart or opening the aorta. The arterial tree is accessed either in the groin or in some cases we are doing very small incisions in the chest to access the apex of the left ventricle, but in either case the heart is left beating, the valve was left in place and simply displaced out to the outside with a new valve placed inside it.

**DR. JANET S. WRIGHT:**

**If you are just joining us, you are listening to Heart Matters on ReachMD, the Channel for Medical Professionals. I am your host, Dr. Janet S. Wright. Our guest today is Dr. Arvind Agnihotri, Assistant Professor of Surgery at Harvard Medical School. We are discussing developments in surgical therapies for valvular disease.**

Dr. Agnihotri you just did something pretty amazing and that's described the deployment of a percutaneous valve on radio. I think all of our listeners got a great picture of that. Talk to us about the access by which that valve is delivered.

**DR. ARVIND AGNIHOTRI:**

Janet, that is a perfect question. One of the biggest issues we have had to date with these various valves is getting adequate access. Despite the fact, that we are able to crimp this stent and valve material down, it still has a significant radial dimension or diameter. The current iteration of the Sapien valve, which is a valve that is in the US trial now requires a 22 or 24-French size and remember French is a circumference in millimeters which means you need about a 7 or 8 mm blood vessel in order to track that device. In this elderly population with aortic stenosis what we found is a lot of people have vascular disease and getting access from the femoral vessels to the heart with a track that has a 7 or 8 mm reasonable type blood vessel, by that I mean a not lot of calcium or protruding material, has been a challenge and there are a lot of people who would otherwise qualify for a femoral approach to the heart in which that is somewhat challenging. In response to that, the other approach that has been developed to place these valves, the first approach from the groin as you could imagine goes retrograde against the blood flow back across the aortic valve, the other approach would be to place the valve antegrade that is with the direction of blood flow. There is 2 ways that one could do that, the first way would be across the venous system and through the inner atrial septum around the mitral valve and through the aortic valve and that was the initial way that these devices were developed. Unfortunately that tracking around the mitral valve particularly was fraught with some difficulties with

injury to that structure. So, the current idea of doing an antegrade deployment is to make a small anterior thoracotomy near the apex of the heart and introduce the device directly through the apex and then through the aortic valve. Again this would be done without heart lung bypass or without cardiac arrest.

**DR. JANET S. WRIGHT:**

Fascinating, the progression of the technology here to serve a set of patients who would otherwise really be miserable from their symptomatic or severe aortic stenosis. As many of our listeners know, that symptom is predominantly shortness of breath and many patients with severe AS feel like a fish out of water, quite dyspneic and the quality of life is miserable with decreased exercise capacity and continuous misery, so this holds great promise. May be you could help our listeners understand who is the ideal candidate for this procedure or perhaps you would want to talk about the trial that is getting started now in the US.

**DR. ARVIND AGNIHOTRI:**

Sure. Well I think in the near future there is going to be an extension of the criteria in terms of who is candidate for this trial. What we are doing right now with this in the US in general is we are looking at one of the potential percutaneous valve devices. It is a valve device that is being developed by the Edwards Corporation, it is a Sapien valve and their trial is called the Partner trial. Of course, I worked at the Partners Healthcare System of which the Harvard Hospital is a member, but that is not related, it is just a coincidence. The Partner trial is aimed at identifying the benefit of this type of a therapy and this device in high-risk patients. So at the moment as part of this FDA trial we are only enrolling people who are really at quite high risk for mortality with traditional surgery. The trial is setup with 2 arms. The first arm would be a high-risk surgical arm versus this kind of a trial in one-to-one randomization. The second arm would be people that we simply would not operate on, inoperable patients and those patients they are going to either get what they would get normally which is best medical therapy or they would be offered this device. The trial is aimed at finding out if in the medical arm if we are better off doing this device than medical therapy and in the surgical arm if we are at least not inferior and hopefully with less morbidity. Because we are looking for really high-risk patients at the moment, they need to have a documented risk of death in the 10% to 15% range and there are some tools that we have developed over time in cardiac surgery to help us mathematically predict the risk and these were based on logistic equations from the Society of Thoracic Surgeons. To give an idea of the risk profile we were talking about, as I mentioned to you we do this operation relatively routinely with a 2% mortality, so to find people at a 10% to 15% risk of death we are really talking about the riskiest 1 out of 20 people.

**DR. JANET S. WRIGHT:**

We have been learning more about surgical treatment and new advances in the treatment of aortic valve disease with Dr. Arvind Agnihotri. Dr. Arvind Agnihotri, thank you so much for being our guest today.

**DR. ARVIND AGNIHOTRI:**

A real pleasure. Thank you.

You have been listening to Heart Matters on ReachMD, The Channel for Medical Professionals. For more information on this week's show or to download a pod cast of this segment, please visit us at [www.reachmd.com](http://www.reachmd.com). Thank you for listening.