

## BroadcastMed | Ventricular Assist Devices (VAD) in Treatment of Advanced Heart Failure

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**RAJIV GULATI:** Hello, I'm Dr. Rajiv Gulati from the Division of Cardiovascular Diseases, Mayo Clinic in Rochester. And I'm delighted today to be joined by Dr. John Stulak, one of our surgeons from the Division of Cardiovascular Surgery.

John has an expertise in heart transplantation and ventricular assist devices, which will be the focus of our conversation today. John, welcome.

**JOHN STULAK:** Thank you very much. My pleasure to be here.

**RAJIV GULATI:** John, many of us remember or are familiar with these great, big, bulky assist devices that were intended just for short-term use in the ultra-sick. Perhaps you can walk us through the evolution from those bulky devices to where we are today.

**JOHN STULAK:** Thank you very much. It'd be my pleasure. There have been significant advances in the field of mechanical circulatory support, or heart pumps, in the last decade, starting with the first generation pumps-- what we used to call first generation pumps, which were, again, these big, large, bulky devices-- the HeartMate I or XVE.

They had limited durability. They were very large, very big procedures to implant. We have now come to what we call the second generation device, which is the HeartMate II.

It's a smaller device, much better durability. And even now, the third generation pumps, which are centrifugal flow devices, which basically you can hold in the palm of your hand-- so much easier to implant. And it's thought that these devices will even have increased durability.

And even starting back with the early trials using these first generation pumps, which were large and bulky, as you said, and had limited durability, there was a significant survival advantage for these pumps compared with best medical management in patients who are not thought to be transplant candidates. And as we improved the durability and surgical expertise, we have consistently shown survival advantage of implantation of these pumps versus medical management for patients with advanced heart failure. So we've come a long way in the field.

**RAJIV GULATI:** And more to come, no doubt, down the line.

**JOHN STULAK:** Absolutely. Again, the devices are getting smaller. They're becoming easier to implant. And the thought is, with less moving parts and less parts that are interacting with each other, that these devices will have even better durability.

**RAJIV GULATI:** Very interesting. Maybe you could take us through-- just take a patient, comes to see you with end stage heart failure. Take us through your algorithm-- your decision making-- as to where they may be suitable for one of these devices and whether it's a destination or a bridge to transplant.

**JOHN STULAK:** Sure. And this decision tree tends to be more of an art than a science. Many options for patients with advanced heart failure. One is heart transplantation.

Another is left ventricular assist devices, or LVADs. And the other is medical therapy. When we're talking about advanced treatment for heart failure, we're talking about heart transplant or VAD therapy.

And we have a big multi-disciplinary team here at Mayo Clinic who evaluates the patients very thoroughly-- their co-morbid conditions, things like that. And typically, what would make a patient what we call destination therapy, where they would receive the pump as their definitive treatment and not as a bridge to a transplant, is usually age-- typically between 65 and 70 is the time when we start to think that patients don't do that well after a heart transplant. And we would recommend a heart pump. Also, if the patient were to have other co-morbid conditions which would preclude heart transplantation, that's what would label them as a destination therapy patient.

**RAJIV GULATI:** Do you think time will come when it will be the first choice for more patients-- for younger, less co-morbid patients?

**JOHN STULAK:** That's a great question. And there are a lot of studies which we are a part of that are examining the earlier adoption of this heart pump therapy, because results are improving and outcomes are better-- that perhaps that we should be implanting these pumps in the less sick individuals. Earlier on, these pumps were basically used as crash and burn salvage therapy.

And we know that patient selection and how sick the patient is at the time of implantation really impacts their outcome. So that is the focus of ongoing therapy.

**RAJIV GULATI:** Very interesting. So these are sick patients with heart failure, multiple co-morbidities, as you say. They already have restricted lifestyle options. How does the addition of a VAD-- a destination therapy VAD-- affect their lifestyle thereafter. How does it impact their daily life? Maybe you could help us with that.

**JOHN STULAK:** Sure, absolutely. Not only do these pumps offer a survival advantage, but they've been consistently shown to impart and improve quality of life. So I think it's a trade-off.

It's very intense therapy and they have many modifications that they need to make to their lifestyle, in terms of no swimming or bathing, because they have a driveline which, as it exits their skin for their power supply, they have a lot of equipment that they need to take care of. And they always have to be thinking, are their batteries charged? Are they not?

They need to be near a power source. And we recommend our patients not to drive, only because there are very few laws to guide us. What is the liability of a VAD patient if they were in an accident-- whether or not they would be held accountable or not. So there's a lot of lifestyle modifications in those regards.

**RAJIV GULATI:** But there's no restriction on an end stage heart failure patient driving.

**JOHN STULAK:** Correct. Not currently. That's right.

**RAJIV GULATI:** OK. And anticoagulation, do they need to be able to take a formal anticoagulation?

**JOHN STULAK:** That's another point. They balance the razor's edge, so to speak. They take blood thinners for the rest of their life, because blood is now going through a foreign surface.

And so they run the risk of, if the blood is too thin, with GI bleeding or other areas of bleeding. Versus if their blood thinning is too less, then they might risk the clotting of the pump and having thromboembolic events. So it's really a fine balance.

**RAJIV GULATI:** So as our population ages, the number of heart failure patients seems to be rising incredibly.

**JOHN STULAK:** That's exactly right. And I think the VAD generation, as I like to call it, is really a growing area of the population. And there are potentially future unmet needs in terms of rehab facilities.

These are very debilitated sick patients. Dialysis units that are comfortable taking care of these patients-- and these patients are now not dying of their heart failure, but aging. And so nursing homes dealing with senile care are also concerns that, as these patients grow older, they're going to be seen more and more where the general public are seen.

**RAJIV GULATI:** Very interesting. Many ethical problems and questions will come down the line. Perhaps we could wrap it up. You could briefly give us an overview of the Mayo experience-- the data that you guys have generated and where we're going from here.

**JOHN STULAK:** Absolutely. So our program has grown tremendously in the last five years. We've implanted almost 200 pumps in the last five years.

Our center is very unique in that most centers that implant these heart pumps, it is done as a bridge to transplant. So they are younger, healthier patients. Their transplant candidates, after all.

Whereas our center tends to see the older, more sick, and more complex patients. Whereas the majority of patients we implant are destination therapy patients. So a lot of times, Mayo Clinic is, quote, "last stop shopping" for a lot of diseases, processes. And this is clearly one and the same.

**RAJIV GULATI:** Well, thank you, John, for joining us. It's been an absolute pleasure. It's been an education for me. And I look forward to hearing updates in the future in this rapidly changing field.

**JOHN STULAK:** Thank you.

**RAJIV GULATI:** And thanks to you for joining us.