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(866) 423-7849

The World's Smallest Heart Pump

The world's smallest heart pump, a ventricular assist device for high-risk coronary interventions. You are listening to ReachMD, the Channel for Medical Professionals. Welcome to The Clinician's Roundtable. I am Dr. Matthew Sorrentino from the University of Chicago Hospitals, your host and with me today is Dr. Michael Siegenthaler. Dr. Siegenthaler is the Associate Professor of Surgery in the Division of Cardiac Surgery. He is the Director of Thoracic Endovascular Therapy and VAD research and the Associate Director of the Artificial Heart Program at the University of Pittsburgh Medical Center.

DR. MATTHEW SORRENTINO:

Dr. Siegenthaler welcome to our show.

DR. MICHAEL SIEGENTHALER:

Thanks.

DR. MATTHEW SORRENTINO:

I thought we would start with just a very general question. Can you explain to our audience what exactly do we mean by a VAD? What is a VAD?

DR. MICHAEL SIEGENTHALER:

Basically, a VAD is a ventricular assist device, which is to just plainly speak a pump, which pumps blood usually on the left side, from the left atrium or from the left ventricular cavity and ejects the blood into the arterial system, either the aorta or a peripheral artery, so it's a ventricular assist device.

DR. MATTHEW SORRENTINO:

So, we usually have thought of these types of devices in end-stage heart disease, the bridge to heart transplant, but I understand there are newer devices and this newest device is called the Impella System. What's different about this system?

DR. MICHAEL SIEGENTHALER:

Well, this system is very, very small. Essentially, the idea came in the mid 80s to a group of engineers that worked at the Helmholtz Institute in Aachen, Germany and they felt that with a micro-axial flow pump that is smaller than a pencil that they will be able to pump 4 to 5 liters of blood and what they did, they submitted for, you know, the correspondent of the NIH. They submitted a grand proposal, which they got and those engineers worked for a couple of years on that and to everybody's surprise, these pumps, which rotate about 30,000 times per minute, did not make the red cells to burst and to cause hemolysis in the experimental animals and what happened with their findings, they ended up founding a startup company, which is called Impella and they have been working on this ever since and has been able to further reduce the size of these pumps, so it is basically a new concept, the so-called axial flow pump, which they reduced to a really tiny, tiny size. It may be important to say that they were not the very first ones to do this type of an assist device. There was a pump, which was called Hemopump, which I think Dr. Wampler developed in the US, which had technical problems, though it was the same principle, it was a micro-axial flow pump, but other than the Impella, this pump had a long wire, which had to be turned with a motor outside the body as opposed to the Impella pump, which has electrical motor, which sits right at the end of a catheter and this catheter mounted. It's like a microelectromotor that then spins this Impella inside of this pump.

DR. MATTHEW SORRENTINO:

So, it's so small that you said it can be inserted via a catheter. So, can you describe how this particular device, how this particular pump can be inserted during, for example, a cardiac catheterization procedure?

DR. MICHAEL SIEGENTHALER:

Yes. So, the cardiologist has to put a fairly large arterial sheath into one of the femoral arteries and then a guide wire is advanced through the iliac vessels up the abdominal and descending aorta around the arch, into the left ventricular cavity and then over this guide wire, this Impella 2.5 is put, this is the smallest model that's currently available, is then advanced over this guide wire through the vascular tree all the way across the aortic valve and the principle how it works is it aspirates the blood at the tip within the left ventricular cavity and then the pump lays across the aortic valve and it ejected into the aortic root the blood and this percutaneous device is able to pump about 2.5 liters per minute.

DR. MATTHEW SORRENTINO:

So, the whole device can be put in percutaneously, we don't need to have any surgical procedure to insert this device?

DR. MICHAEL SIEGENTHALER:

That's right, for the 2.5 device. There is also a 5.0 device, which has about 6 mm in diameter, so it's like a normal pencil. This device can be placed after a small groin cutdown, also in the cardiac cath lab and has been used extensively in Europe for patients who have acute cardiogenic shock with a large myocardial infarction and scenarios like that.

DR. MATTHEW SORRENTINO:

If you are just joining us, you are listening to The Clinician's Roundtable on ReachMD, the Channel for Medical Professions. I am Dr.

Matthew Sorrentino and I am speaking with Dr. Michael Siegenthaler and we are discussing the Impella, a new type of ventricular assist device that can be placed into the left ventricle percutaneously.

So, if we have this ability to put this Impella device during a cardiac catheterization procedure, what type of procedures, what type of patients can you see a use for this type of device?

DR. MICHAEL SIEGENTHALER:

Well, the way the approval started in the US will setup is that basically they try to show non-inferiority compared to intra-aortic balloon pump support. So, they designed the so-called Protect Trial, which randomizes high-risk angioplasty, coronary intervention patients with a reduced ventricular function into either balloon pump therapy versus Impella 2.5 support.

DR. MATTHEW SORRENTINO:

So, this was high-risk patients, patients who had acute coronary syndromes or needed to have a very complicated angioplasty who received the device?

DR. MICHAEL SIEGENTHALER:

Yes, these are patients who have like left main coronary stenosis or just one-vessel runoff and the EF that's below 30%, so truly high-risk patients and usually they were not surgical candidates these patients, they were not acute MI patients in cardiogenic shock, that's a different study that's being evaluated in Europe right now, but not in the US.

DR. MATTHEW SORRENTINO:

So, how did the Impella device compare with balloon pump, did we have similar outcomes with both devices?

DR. MICHAEL SIEGENTHALER:

Well, see the company was running the approval process on 2 tracks. On one hand side, they designed this study, which in the Protect Trial, they want to enroll a lot of patients, I think it's something over 400 patients that they want to randomize and we are currently somewhere below 100 patients, so it's 654 patients in the 150 sites that they wanted to randomize. So, the trial is still ongoing currently, but simultaneously the company also filed for a what's called a 510(k) approval process, which is basically a process where they say this technology has been used in a similar fashion in humans before and it's like an analog technology approval process and they recently have received the 510(k) approval. So, this study is still ongoing, but the device in the meantime has been approved for use in people, in humans.

DR. MATTHEW SORRENTINO:

So, if you are in the cath lab and you have a high-risk angioplasty and a patient has a cardiac arrest during the procedure. If the Impella device is in place, can it maintain cardiac output so the patient's hemodynamics can be maintained during that time?

DR. MICHAEL SIEGENTHALER:

This is a very, very important question and we have to be aware that Impella is truly what it's called an assist device. It's not a cardiac replacement device. We did a multi-center study in Europe when I was still working in Triberg, Germany, with this device and we looked at postcardiotomy patients that were supported with this device and we made a striking finding that what we did, we measured the cardiac output with a Swan-Ganz catheter and we looked at the Impella device flow that you can read on the device console and what we found is that if the patient has 1 liter more cardiac output than the device is pumping, I will give you an example, the Impella device pumps 4 liters and the total cardiac output is 5 liters, then we said this patient's estimate residual cardiac function is 1 liter, that means he has some remaining cardiac function that's able to eject on top of the Impella device. If we had patients who had an estimate residual cardiac function of more than 1 liter, we had an extremely high survival rate of 90% and that was in a patient population that would have had a predicted mortality of 80%. They all couldn't be separated from cardiopulmonary bypass after open-heart surgery. On the other hand, if the patient had an estimate residual cardiac function of less than 1 liter, it's really striking that most of these patients did not survive. So, to answer your question, if a patient has a malignant ventricular arrhythmia or a cardiac arrest while the PTCA is performed or the stent is placed, then this device will maintain a blood pressure, will maintain hemodynamics and buys the cardiologist time to correct whatever is not good with the coronary flow at that point. However, if the patient comes in several hours into a large, let's say, anterior wall myocardial infarction and virtually has no cardiac function, then this device probably will not help the patient to survive. It's simply an assist device and cannot replace the entire left ventricular function.

DR. MATTHEW SORRENTINO:

Now, some times we will leave intra-aortic balloon pumps in for a day or two or three while we try to improve cardiac function. Can the Impella device be left in longer than the procedure? How long can it be left in a patient to assist the ventricle?

DR. MICHAEL SIEGENTHALER:

You know, it's the same as with the pumps that got approval like 30 years ago for ECMO. All these devices seek approval for a short time and then what happens, the physicians who use it, use it longer. So, the approval that Impella submitted was up to 5 days and it was the same in Europe. This device was approved for 5 days, but when we looked at our series, we had several patients who were supported 8 to 10 days and had no adverse events related to that for long duration of support. So, by all means if a patient has marginal cardiac function, just had a high-risk PTCA, they can keep that Impella device in place to get some ventricular support until their myocardium has recovered.

DR. MATTHEW SORRENTINO:

One of the contraindications to balloon pumps was patients who have severe aortic insufficiency. Does the Impella device have the same problem in patients who have aortic valve disease?

DR. MICHAEL SIEGENTHALER:

Aortic valve insufficiency per se probably isn't a contraindication. However, if a patient has one of those sclerotic thickened aortic valves or aortic stenosis, then it's contraindicated. The reason why is that this device depends upon, you know, pliable soft aortic valve leaflets that can close around it, so there is not much aortic valve insufficiency by this catheter that goes across the valve. If you have a thickened sclerotic leaflet, however, you would have to anticipate that you will get massive aortic valve insufficiency and therefore it

shouldn't be used in such patients. Also, it shouldn't be used if patients have thrombi in their left ventricular cavity for obvious reasons, you would probably dislodge that thrombus and then cause thromboembolic complication of the device.

DR. MATTHEW SORRENTINO:

This will be a fascinating area to watch in the future to see how we can help many of these very sick patients.

I want to thank Dr. Michael Siegenthaler, who has been our guest. We have been discussing the world's smallest heart pump, the Impella device, which has now been approved for high-risk coronary procedures. I am Dr. Matthew Sorrentino. You have been listening to The Clinician's Roundtable on ReachMD, the Channel for Medical Professionals. Please visit our website at reachmd.com, which features our entire library on on-demand podcast and thank you for listening.