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Treating Tricuspid Valve Regurgitation with Novel Replacement Device

Dr. Butler:
Tricuspid valve regurgitation is a complex condition that normally doesn't show signs or symptoms until the severity of the disease has increased. However, for the first time in the United States, cardiologists at Henry Ford Health have successfully completed a procedure that implanted a novel transcatheter tricuspid valve replacement device.

You're listening to Heart Matters on ReachMD. I'm Dr. Javed Butler. And joining me today is Dr. Pedro Villablanca who is a structural heart interventional cardiologist at Henry Ford Health. We'll be discussing this novel technology and how it works.

Dr. Villablanca, welcome to the program.

Dr. Villablanca:
Thanks so much, Javed. I'm happy to be here, and hopefully, we get a great conversation about tricuspid regurgitation and the future transcatheter technologies that we have for the next decade.

Dr. Butler:
Absolutely. On behalf of our audiences and for myself as well, I look forward to learning from you. So let's start with some background. Can you tell us what are the symptoms of patients with tricuspid valve disease and some sort of a natural history? Do they develop symptoms right away? Does it take a long time, the severity? Just give us a little bit of a sense.

Dr. Villablanca:
Right. So as you know, as compared to left-sided heart disease that which gives you more, I would say, symptomatic or early symptoms when the mitral or the aortic valve fails, the tricuspid valve, actually, is a valve that might take years and decades sometimes to manifest, and when it does, sometimes, it's too late, too advanced, and the options are not many. And the symptoms that you can get from tricuspid regurgitation include fatigue, leg swelling, and abdominal bloating. When you have it really advanced and it's come from the left side by pushing the interventricular septum, you can also have shortness of breath and go into a cycle of pulmonary hypertension from diastolic dysfunction and have pretty advanced heart failure at that point.

Dr. Butler:

So who might be the patients who are at risk for getting these problems?

Dr. Villablanca:
So the patients that might be at risk, actually, include a variety of patients; patients with left-sided valve disease with mitral insufficiency, stenosis, or aortic stenosis because the heart is a pump like a tube. So once the exit valves, either the mitral or the aortic start failing, that pressure gets pushed backwards into your lungs and then your right side, and that can affect tricuspid valve. Also, patients with longstanding atrial fibrillation, patients with pulmonary disease as well, can get affected, so there's a variety of disease that can cause it from the heart and the lungs.

Dr. Butler:
So let me ask you a question for which I don't think there is a real easy answer, but maybe you have a perspective. These people who develop these symptoms, how much of that is tricuspid regurgitation versus the effect of tricuspid regurgitation on the right ventricle, and it's the right ventricle failure that develops the symptoms versus tricuspid regurgitation itself? Or do you think it's a totally artificial distinction?

Dr. Villablanca:
I think that's a great question. I'm not sure we have a clear cutoff. I guess when you have a primary tricuspid regurgitation, the problem is at the leaflet itself. That's the minority in my opinion. That's a clear cut point. When you fix the tricuspid valve, patients do feel better, and it's likely attributed to the valve itself. However, I would say the minority of this tricuspid regurgitation, it's a consequence of the RV dilatation, either from the disease that we mentioned before or lead wires, and sometimes even if you fix the tricuspid problem, the etiology, those patients have already established RV failure, so the symptoms might not resolve completely, but you might either improve their New York class and prevent the progression of this getting worse. But again, there's a point where it's pretty advanced, and even if you fix the disease, you might still have residual symptoms, and the patient needs to be aware of that.

Dr. Butler:
For those just joining us, you're listening to Heart Matters on ReachMD. I'm Dr. Javed Butler, and I'm speaking with Dr. Pedro Villablanca about patients with symptomatic tricuspid valve disease.

So let's move on to some therapeutic options here. So I'm really excited to talk to you about some of the really cutting-edge work that you're doing. But before we get to that, tell me what are the therapies available for the patients today as a standard of care?

Dr. Villablanca:
So the only standard of care that we have so far is surgery. And when patients go for heart surgery, it's very rare to get isolated tricuspid valve replacement or repair. A lot of the time, as we mentioned before, these patients, they come with a pretty advanced disease, and they're not a surgical candidate, and if they are, the mortality over the last decade has been around 10 percent, so it's a pretty morbid surgery, and that so far is the gold standard is a ring that most surgeons like to repair the valve to prevent knocking the septum and getting a pacemaker or the replacements in cases, I would say, when you have infected endocarditis and you have to replace the valve.

And from there, us structural cardiologists, we've been lucky on some occasions when those rings or valve fails to be able to put a transcatheter valve, a valve from actual TAVR valves that help those patients recover the functionality of the valve. However, those are the minority of the patients. As I mentioned before, not everyone gets a tricuspid valve replaced or repaired by surgery. So most of the valves that we're facing with failure are native valves, and that's where structural heart technology has been evolving pretty fast, and hopefully, we can get options in the near future available to everyone.

Dr. Butler:
Yeah. What you just said is so important, and that's probably one of the biggest reasons that most patients with tricuspid regurgitation up until now, really got no treatment per se, overall. But let's turn our attention to this new transcatheter tricuspid valve replacement device. Can you tell us more about this device? How do you implant it, the minimally invasive procedure, and experience that you have had?

Dr. Villablanca:
Right. So just as a quick background, the options that we have so far for tricuspid valve transcatheter therapies are part of trials. There's nothing approved commercially by the FDA or CMS yet. At our institution—and the rest of the world, I guess—we're faced with this tsunami of tricuspid regurgitations without options, and many of these patients were not included in the trials because of comorbidities, for example end-stage renal disease or advanced left-sided disease, that would preclude them from getting enrolled into a trial, and also, some of them didn't have the anatomy to be considered for the trial. And given those circumstances, we're one of the major centers in the U.S., I would say, and the major in Michigan that we get a lot of referrals. We explore non-U.S. pathways to help patients, and one of them was the LuX-Valve that was initially implanted via transatrial, like a hybrid approach in China and implanted in the tricuspid valve to replace the valve.

Over the last years, they developed the purely transcatheter replacement from the right IJ where everything is done without surgical catheter. Everything goes from skin to skin with a percutaneous technique, and we deploy a valve from the neck, which anchors on the septal wall of the right ventricle with some needle pins, and then it has two tabs that anchors below the anterior or the posterior lip of the tricuspid valve, and then it has a bigger atrial security that helps sealing any PVL, and also preventing from this valve migrating ventricular.

Dr. Butler:
This is really exciting stuff and really cutting edge. So over the last decade we are really focusing in all areas of cardiovascular medicine on quality of life and patient-reported outcomes as well. So can you tell us a little bit about what you project these procedures will do in terms of tricuspid regurgitation patients, their symptom burden, and their quality of life?

Dr. Villablanca:
Right. So as we all heard from TRILUMINATE trial, which shows an improvement in tricuspid regurgitation severity and quality of life, I think what we're going to be seeing with most of these transcatheter technologies is something similar, and the main reason for that is the time we're intervening on these tricuspid once—as you know, most of the cardiovascular diseases, if you catch them early, the chances of early major improvement, either in terms of survival and quality of life, would be much higher. However, when you treat them in a more advanced stage, you might not impact the survival, but you might impact the quality. So I do believe that most of these replacements and repairs that we're going to see with transcatheter will have an impact on quality, and to see an impact of survival, we might have to wait at least five years to see the difference between those patients that did not receive a transcatheter option versus the ones that received one.

Dr. Butler:
But I have to say that you're taking on a really challenging problem, but we do need people to help us with that. So before we close, can you just give me sort of how you see this field evolving between percutaneous replacement versus repair? Where is this whole field going?

Dr. Villablanca:
So I think where the field is moving, as you've seen in the aortic valve, we will have to standardize patients more than based on the severity of the jet or incorporating the severity of the jet of the tricuspid regurgitation. The impact of how that tricuspid regurgitation has affected the ventricle or the atrium in some instances and not just based on symptoms because if we wait for symptoms, it might be too late. Having said that once we have a better understanding of the natural history and not just based on symptoms, but also, how the heart gets affected and sometimes other organs.

If we keep receiving patients the way they're being sent now on a more advanced stage II/III of tricuspid regurgitation with RV dilatation, most of them will benefit from replacement. I would say from 100 patients that we screen here, for example, only 10 percent might be a candidate for edge-to-edge repair because they already are at advanced stage where the RV is dilated and the annulus. So you might fix some of the leak, but they might keep growing, and then you might get new leaks in between the clips or the PASCAL. So I see mainly a major role for replacement, and we will have some role for repair in patients where the gap, it's less than eight, less than seven, depending on who you're quoting.

And then I think as these technologies keep evolving, we might see hybrid procedures with a ring-like technology, follow with edge-to-edge repair, and maybe the noninvasive, I will call primary cardiologists would have a better insight and even internal medicine or family medicine doctors that refer these patients early to get better outcomes and better quality of life.

Dr. Butler:
Great. Well, Dr. Villablanca, it was really great speaking with you today, and thank you so much for working on all of these cutting edge technologies and trying to find solutions for our patients that are really symptomatic, and we really don't have a lot of options today, so I appreciate all your work. Thank you for talking with me today.

Dr. Villablanca:
Thanks to you, Javed, and hopefully, we have another occasion to talk more about structural heart disease. It was a great talk.

Dr. Butler:
For ReachMD, I'm Dr. Javed Butler. To access this and other episodes in our series, visit ReachMD.com/HeartMatters where you can Be Part of the Knowledge. Thanks for listening.