

Title: EuroPCR 23: DRAGONFLY-DMR: Safety and Effectiveness of Dragonfly TMVR System for Mitral Regurgitation

Participants: Dr Scott Lim

Date: 17/05/2023

Dr Scott Lim

"I'm Scott Lim. I'm a cardiologist at the University of Virginia in Charlottesville in the United States, and I've been involved in structural heart disease focusing on mitral and tricuspid valve disease for the last few years.

What is the background and rationale behind this study?

The idea behind this is transcatheter mitral valve repair is most done by something called TEER, Transcatheter edge-to-edge repair. The original TEER device was a Mitraclip. It's evolved over time to the latest generation of mitaclip. And now the next thing we have is Pascal, and the next thing past that is this novel Dragonfly mitral TEER device. And that's what this trial studied.

What is the unique feature or design of the study device compared to other transcatheter edge-to-edge repair devices?

Yeah, there's three key unique differences for this device. One, it is a very robust mechanical closure of the grasping arms to bring the leaflets together. Two, it has a central part that is very soft and distensible. So, as you bring the arms and the anterior and posterior leaflet together against it, that distensible part is compressed and spreads out medially and laterally on the valve to further block the regurgitation orifice. The third unique feature isn't the device, but the delivery system, which is an indexed articulating delivery system. So, it can be very controlled, very repeatable, and easy to teach newer operators with this device.

How was the study designed, and what were the baseline characteristics of the patients included in the study?

So, we first did an early feasibility study, which was completed and previously presented. Now, what we've just done and just presented is the pivotal trial of using Dragonfly in the subset of patients with mitral valve disease that have degenerative, meaning prolapse and flail of their mitral valve.

What are the key findings presented at EuroPCR, and what conclusions can be drawn from them?

We enrolled 120 patients at 27 different centers throughout China in this pivotal study. And this is the next step with further trials investigating other subsets like functional MR or even patients with tricuspid valve disease. And then we're now - next step, of course, is bringing the device to Europe and other geographies and exploring it further. The trial enrolled 120 patients. We're following them, all of them out to five years. But this point was a prespecified point where we could look at the data at one year. So, every single patient was followed up, had an independent eligibility committee and an independent echo core lab adjudicating the results, both to get the patients in the trial as well as what their results were at the one-year mark. And that's the data we just showed today.

What are the next steps?

I think one of the most important things is this is more important information showing that TEER, as a concept, is safe and efficacious, particularly with a Dragonfly device, for getting it in the hands of relatively new operators to doing TEER therapy in China. They can show that they had a very high procedural safety as well as very good efficacy in terms of reduction of the MR and how that translated to helping the patient's ventricles get better as well as overall quality of life for the patients."