IMMREVIEW

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The tricuspid valve: Forgotten no longer.

Ventricular view of a porcine tricuspid valve

IMMR Accelerating your innovative research

The tricuspid valve: Forgotten no longer.

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Indeed, the tricuspid is no longer the forgotten valve. After being lucky enough to be there when TAVI (transcatheter aortic valve implantation) was born 20 years ago and tested by the "founding fathers" at IMMR, we saw the mitral being seen as the next new frontier. The phenomenal development of structural heart intervention was launched. Although we started working on tricuspid projects as early as 2004, this endeavor has now become very busy, with strategies of all sorts, be it for repair or replacement.

Prof. Hendrik Treede has been involved in many R&D structural heart projects at IMMR over the past decade. We greatly enjoy working with him and thank him for sharing with us a bit of his insight on the present and future of the tricuspid landscape.

Welcome Prof. Treede. Is the need for treating independent tricuspid valve disease sufficiently recognized in the medical community?

I think it has changed for the positive within recent years, and the tricuspid valve can no longer be called the forgotten valve as it was for a long time. We now have much more data about tricuspid valve disease and it has found its way into surgery guidelines: It is now clearly defined when tricuspid valve repair is indicated, especially in combination procedures. Still, the need to treat isolated tricuspid regurgitation (TR) is not fully embraced. The reason is that surgical results for isolated tricuspid repair or replacement have not been very good, with reported mortality rates up to about 10%, which of course is quite high. This is where transcatheter-based technologies come into play and have shown promising results.

On the surgical side we now begin to perform tricuspid valve repair minimally invasively at the beating heart, a technique that is completely different from an open chest, arrested heart tricuspid valve operation. We are now accumulating data on these new kinds of procedures and we see that the mortality rate is much lower, comparable to that of catheter-based technologies. With this, we can say that severe isolated TR should be treated either by beating heart surgery or by intervention.

What are your thoughts about how rapidly the tricuspid valve market is growing?

My impression is that it moves quite quickly. The TriClip is now CE-marked for TR so an experienced MitraClip implanter can now also implant TriClip. But I don't see this growing the same way than the MitraClip because tricuspid procedures are much more difficult and the results are not yet uniformly excellent.

Prof. Dr. med Hendrik Treede is the head of the Department of Cardiac Surgery at the University Hospital in Bonn, Germany. He shared with us his thoughts on the current landscape for transcatheter tricuspid valve repair and replacement.

Atrial surgeon's view of a porcine tricuspid valve

THE TRICUSPID VALVE CAN NO LONGER BE CALLED THE FORGOTTEN VALVE...

IT IS CRUCIAL THAT WE TREAT TR PATIENTS AND TREAT THEM EARLY; THE MARKET FOR TR COULD EVEN EXCEED THE MITRAL MARKET.

Even in the hands of experienced specialists, about 50% of patients may still be left with a severe-or-higher degree of TR with current technologies. Unless we're able to improve outcomes, the market growth might not be sustained. When it comes to catheter-based technologies, we need devices that are specially designed for the tricuspid valve to achieve the best results.

When we speak about treating tricuspid disease, right ventricular function is an essential part of the decision process. It is crucial that we treat patients early, before they develop signs of right heart failure. Once we show that early treatment of moderate to severe TR is beneficial for patients, this may become a big driver for the market, many more patients could be treated and the market for TR could even exceed the mitral market.

Do you think that the tricuspid valve is more suited to a repair or a replacement procedure?

There are two ways of looking at it: from a surgical perspective, we should always try to repair the valve. The atrioventricular valves contribute to left and right heart function, and if you replace them with a prosthetic valve then some of this function is lost. Surgically, this is not very difficult with the technologies that are available today. There are many techniques for leaflet repair and annuloplasty allowing for tricuspid valve repair in the vast majority of patients, especially in functional TR which is the majority of cases.

From the transcatheter-based perspective, the situation is much different because we don't have the optimal tools yet and outcomes are sometimes disappointing. So, from a transcatheter perspective, I would say that replacement technologies have a higher potential today, until we have devices that work well for tricuspid repair.

What are the technologies that you think are showing the most promise right now?

For tricuspid valve replacement my impression is that devices with a dual stent design work best because the tricuspid valve annulus is such a large structure and is so variable. In a dual stent design a conformable outer stent can suit any anatomy while the inner stent carries a regular sized valve that is suitable for most patients. I think this kind of design is most promising, but we don't have sufficient data yet to finally confirm this.

Is there any potential for using synthetic leaflet materials?

The use of non-biological material for leaflets may be a very good idea on the right heart side, because the pressure is so much lower compared to the left side. We have seen this with pulmonic valves, where biodegradable or even synthetic materials were used, so this could potentially work on the tricuspid side too. I'm not yet aware of a program pursuing this, but I think it could be feasible.

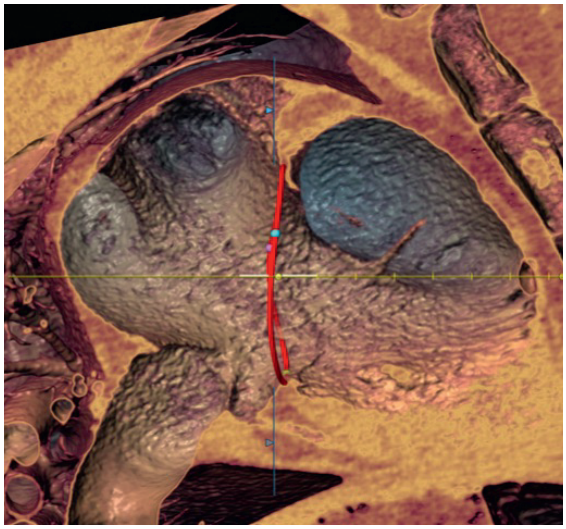
FOR TRANSCATHETER CASES, TODAY REPLACEMENT HAS HIGHER POTENTIAL, UNTIL WE HAVE DEVICES THAT ARE SHOWN TO WORK WELL FOR TRICUSPID REPAIR. WITH TRANSCATHETER TECHNOLOGIES, WE HAVE AN OPPORTUNITY TO THINK OUT OF THE BOX AND TRY SOMETHING COMPLETELY DIFFERENT FROM WHAT IS DONE SURGICALLY

What are some of the important considerations regarding species selection for preclinical studies with tricuspid valves?

The tricuspid valve is quite challenging in animal models. For chronic studies, sheep are the best choice because they won't typically outgrow the valve since they're fully grown adults.
Still the sheep model is not a perfect model for tricuspid work because the atria are very small, the V-shaped right ventricle is hypercontractile, and there is a moderator band that crosses the right ventricle. So, it's a very hostile anatomy for tricuspid valve implantations, but if a valve is successful in this model it holds a lot of promise. I am very interested in the model of right heart failure that IMM Recherche is developing aiming for graded right ventricular dilatation. Once it's developed to a stage where it's ready for use, it will be very valuable.

You mentioned that some technologies that have been adapted for tricuspid valve procedures, like TriClip, are now CE marked for this use. Do you know when we might expect to see the first dedicated tricuspid valve repair or replacement products on the market?

The new tricuspid technologies are still mostly at the stage of early feasibility clinical trials in humans. Interestingly, though, the path to market for replacement devices might be smoother compared to mitral replacement technologies because the tricuspid valve is easier to access, and patient selection is more straightforward because RVOT obstruction is less of a concern.



CT-scan lateral view of the right heart in an ovine tricuspid insufficiency model

Is there any other valve technology that you're looking forward to seeing more of?

Right now, transcatheter technologies mostly try to mimic surgery. While this can work well, we should perhaps take the opportunity to think out of the box and try something completely different.

The hemi-valves that we are seeing today are a good example: only a segment of a valve is placed on the posterior mitral annulus covering the posterior leaflet and enhancing coaptation.

Such new approaches are different from what we do in surgery, and may become very successful catheter-based solutions.

Prof. Treede, it's been a pleasure speaking with you, and thank you very much for sharing your insights with us!

You're very welcome.

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Editor: Nicolas Borenstein
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