

AN INTERVIEW WITH...

Ulrich Schäfer, MD

Prof. Schäfer shares updates on the current status of therapies for each of the four heart valves, as well as new technologies to address heart failure and more.



In 2011, you coauthored an article in *Cardiac Interventions Today* on the state of percutaneous mitral annuloplasty, concluding that indirect, coronary sinus-based devices would only play a minor role in the mitral repair landscape.¹ Do you still believe

this is the case today, or has the technology come far enough that it might play a more significant role than originally anticipated?

The currently available data have not changed my view of indirect annuloplasty devices. Their efficacy is too low to become a significant player in the field of mitral interventions. Out of three candidates (Monarc [Edwards Lifesciences], Viacor [Viacor, Inc.], and Carillon [Cardiac Dimensions, Inc.]), only the Carillon mitral contour system has been able to enter the market in Europe (via CE Mark), whereas the Viacor percutaneous transvenous mitral annuloplasty system and the Monarc system have been removed from the field due to their low efficacy and high complication rates. The Carillon device has shown an acceptable complication spectrum, but even the current REDUCE FMR trial, a randomized sham-controlled study, hardly demonstrated convincing data (mitral regurgitation change: 50% improved, 23.5% worsened, 26.5% unchanged). In fact, the primary endpoint (reduction in mitral regurgitant volume) was just met, with a decrease of only 7.1 mL/beat in the treatment arm. The limited efficacy of percutaneous mitral indirect annuloplasty in functional mitral regurgitation is related to the limited proximity of the coronary sinus to the mitral annulus and therefore offers a nonideal solution to treat mitral regurgitation. Hence, my suspicion in 2011 has been proven so far.

Based on your experience in the TRAVEL registry, what are your top tips for avoiding periprocedural transcatheter heart valve embolization and migration?

Despite the low incidence of transcatheter heart valve embolization (1%), the associated risk of adverse out-

comes is unacceptably high (mortality, 18%; stroke, 10% in the TRAVEL registry).² Interestingly, the occurrence of aortic embolization is four times more frequent than ventricular embolization, and the use of self-expanding or first-generation prostheses, as well as the presence of a bicuspid aortic valve, seem to be independent predictors of transcatheter heart valve embolization/migration.² In addition, we have already described that without calcium (ie, pure aortic regurgitation), the very early risk of device embolization—despite feasibility—is very high (25% with the first-generation CoreValve [Medtronic]).³ Second-generation devices seem to be superior compared with first-generation devices to treat pure aortic regurgitation,⁴ and we have found the JenaValve technology (JenaValve Technology GmbH) with its clipping mechanism to be of particular value during transapical⁵ and transfemoral⁶ implantation.

With this in mind, particular caution needs to be taken in such anatomies. The most important tip is to understand any hostile anatomy preemptively and to be prepared if embolization does occur. Bailout measures, including repositioning attempts using snares or miscellaneous other tools, multiple valve implantations, and conversion to surgery all need to be available and tailored in the interest of the patient.

How large of a problem is the issue of degenerated surgical aortic valves at this time?

To what degree do you see the incidence increasing over the next 5 to 10 years? Do we currently have reliable treatment options to address it?

Treatment of degenerated surgical aortic valves is increasingly becoming a topic of interest because mechanical valves have been largely replaced as a treatment modality in most patients. I believe that we have excellent treatment options today to address degenerated biological valves with various transcatheter heart valves (ie, valve-in-valve [ViV]). As a general rule, we need to respect that the smaller the surgical bioprosthesis is, the higher the risk will be of subsequent prosthesis-

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patient mismatch (ie, those with high gradients). Of note, we can partially reduce this risk with self-expanding technologies using a supra-annular valve function, as seen in the VIVID registry and the most recent VIVALL study.⁷⁻⁹

Concerning the sinus width and coronary height, the fracturing of surgical valves gives an additional value to significantly enlarge the opening areas with the elimination of mismatch findings. Nevertheless, the risk of coronary malperfusion mandates a detailed analysis of a multislice CT scan before treatment in every case. Besides surgical aortic valves, bioprosthetic valves in any position can be addressed today. I believe that ViV treatment of such valves in addition to degenerated transcatheter heart valves will become a very frequent methodology in the coming years and will likely increase from 4% to 6% in 2018 to 20% to 30% in 2025.

Are there any differences in how you would approach a ViV procedure in a rapid deployment surgical valve versus one that was conventionally implanted?

Rapid deployment surgical valves have limited stability within the decalcified aortic annulus (usually a few stabilization stitches) and unfavorable designs for current CE-Marked transcatheter heart valves. Due to the upper stent design of rapid deployment surgical valves, balloon-expandable valves, as well as any of the CoreValve-like designs (ie, Evolut R/Pro [Medtronic], Portico [Abbott]), are suboptimal for ViV implantation.¹⁰ In this regard, a more tubular stent design, such as the Allegra valve (NVT AG), seems to be of particular interest.⁹ Nevertheless, pulling on the catheter needs to be avoided to eliminate the risk of dislocation of the rapid deployment surgical valve into the aorta. Hence, resheathability would be a desired feature in the future for these valves, with limited anchoring within the anatomy. I'm not a believer of rapid deployment surgical valves because the invasiveness of open heart surgery is applied to a prosthesis with similar limitations to those of transcatheter aortic valve implantation (TAVI) (ie, higher risk of paravalvular leaks and conduction disturbances).

What is the most exciting new minimally invasive therapeutic concept to address heart failure that you are aware of or have been able to study?

I think that shunt devices (left atrial decompression) and implantable pressure sensors are the most recent concepts with the highest impact. Anything that is truly minimally invasive will be highly appreciated by heart failure patients, who are at particular risk of procedure-related stress, as the chronically impaired myo-

cardium does not tolerate much in terms of procedural load. We recently implanted the first V-Wave interatrial shunt device (V-Wave Ltd.) in Germany¹¹ and one of the first V-LAP left atrial pressure monitoring devices (Vectorious Medical Technologies Ltd.) in patients at Marienkrankenhaus in Hamburg, Germany,¹² and I was impressed by the simplicity, low invasiveness, and benefit associated with these concepts. In addition, I have performed the world's largest series of left ventricular partitioning using the Parachute device (CardioKinetix Inc.). The results were very promising, with an immediate increase in stroke volume by 30%.¹³⁻¹⁵ Unfortunately, the device was removed from the market due to a complicated United States study (Parachute IV trial), despite its simple TAVI-like implantation concept.

What is the current status of pulmonic valve replacement, and do you see it following a similar trajectory as the aortic, mitral, and tricuspid valve repair/replacement technologies?

The status of pulmonic valve replacement is still behind due to the smaller market potential (ie, fewer patients) for the medical device industry. Nevertheless, pulmonic valve implantation in patients with previous surgical correction of congenital pulmonary valve stenosis, as well as acquired disorders, is a very rewarding intervention.¹⁶ Redo open heart surgery carries a high surgical risk in these much younger patients, and thus minimally invasive catheter treatments are particularly beneficial. We have performed many pulmonic valve implantations using the Melody (Medtronic) and the Sapien (Edwards Lifesciences) technologies with very good outcomes. Nevertheless, it needs to be emphasized that specific expertise is necessary to do these interventions without incurring potentially fatal complications (eg, calcified homograft perforation). Compared with TAVI and other mitral interventions, pulmonic valve replacement with catheters will similarly overtake surgical options in the future.

In what ways have techniques and technologies adapted to suit the particular anatomic features of the tricuspid valve, and what areas are the current major hurdles to fine-tune? Who are the optimal candidates to receive this treatment right now?

Tricuspid valve intervention is still in its infancy.¹⁷⁻¹⁹ But, if carried out with success, it translates to significant benefit for the patients.¹⁷ Currently, we have only a single technology with CE Mark approval (Cardioband, Edwards Lifesciences), which has proven efficacy with a very satisfying safety profile.²⁰ Nevertheless, the 3- to 5-hour

intervention associated with implantation of this device is by far too lengthy to be truly called minimally invasive. It also necessitates a long radiation exposure time for patients and interventionalists. Repair over replacement would be of primary interest if the procedure is simple to perform. Unfortunately, none of the current clinically tested repair devices (including edge-to-edge repair) meet the criteria for ease of use. In addition, there are still unsolved imaging obstacles, with interventionalists experiencing significant visualization problems during repair. On the other hand, the problems with replacement are the topographic neighborhood of the conduction system, embedded pacemaker/implantable cardioverter-defibrillator leads, and most importantly, the asymmetric anatomy with a limited anchoring possibility at the septal site being in close proximity to the right ventricular outflow tract (RVOT). Hence, the risk of device migration into the RVOT, as well as obstruction of the RVOT, needs to be solved. Despite these hurdles, I believe that replacement is likely to become the first-line treatment in the future if a safe and easy concept is found.

Because isolated surgical repair still carries an almost 10% mortality rate, the potential market for catheter-based solutions is huge. Currently, only elderly surgical-high-risk patients are selected for catheter-based solutions,¹⁷⁻¹⁹ but this is likely to change in the next few years.

What are your thoughts on radial access for structural interventions? Which procedures or patient characteristics might make radial access a viable option?

The main limitation of radial access is the small diameter of the radial artery. Devices larger than 8 F will never be applied through a radial approach. Hence, radial access will be reserved for ancillary devices such as embolic protection devices or angiography catheters. With this limitation, transvascular access will be applicable only at a more proximal site such as the axillary artery, which we had previously proven as the first investigators to be suitable for a truly percutaneous approach.^{21,22} With the availability of second-generation closure devices such as the Manta vascular closure device (Teleflex),²³ the percutaneous transaxillary approach for TAVI carries a high potential as a second-line treatment after transfemoral TAVI.

What one passion outside of medicine do you wish you had more time to pursue?

I love painting and the arts. In the past, my wife and I spent many hours and days in our small atelier (<http://erika95atelierhh.blogspot.com>) in Hamburg. Due to many time constraints with my recent job, only my wife is currently painting (abstract arts) and selling to

international clients. She is doing this with great success, and I'm very proud of her. ■

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