AN INTERVIEW WITH...

Ralph Stephan von Bardeleben, MD

Dr. von Bardeleben provides insight into ongoing mitral valve trials and discusses use of mitral devices for tricuspid disease, as well as imaging protocols for transcatheter mitral valve interventions.

Is it common practice in Germany for a heart valve team to direct individual patients to surgical or interventional mitral valve procedures based on their individual risk/benefit ratio and profile? What is the makeup of this team, and do they have other duties besides assessing patients for procedures?

In Germany, the local heart team includes one heart surgeon, preferably involved or lucent to both surgical and interventional strategies, as well as an interventional cardiologist experienced in percutaneous valve interventions and surgical therapeutic strategies. The team is dynamically expanded to fellows of the valvular wards, imaging specialists, cardiovascular anesthesiologists, and heart failure specialists. Psychocardiologists, neurologists, and geriatricians are involved as needed. The team assesses and discusses patient treatment pathways and is involved in both surgical and interventional procedures for treatment of valvular heart disease.

As the COAPT trial nears its projected completion date, can you give us any updates on how the trial is progressing, when early data might be announced, and what you expect to see in these results?

The COAPT trial is nearing completion and is remarkable for its size, increased to 610 patients, and patient inclusion. Trial completion is expected around the third quarter of 2017 with more than 530 patients randomized at this time. We expect to see updates presented on patient profiles as well as on the severity of functional mitral regurgitation and impairment of left ventricular function at the Transcatheter Valve Therapies and the Transcatheter Cardiovascular Therapeutics conferences this year.

The RESHAPE-HF2 trial, formerly RESHAPE-HF, was converted from an industry-sponsored to an investigator-sponsored study. Why did this happen, and how is it designed to study the economic impact of using the MitraClip device (Abbott Vascular)?

The RESHAPE-2 trial was converted into an investigator-initiated study in 2015 due to a low enrollment rate in RESHAPE-HF, which recruited only 42 patients. The trial concept of this European trial resembles the United States COAPT trial in the comparison of percutaneous treatment of functional mitral regurgitation with the MitraClip device versus guideline-aligned optimal medical therapy and then randomization to continuation of medical therapy or MitraClip implantation. Like in the United States trial, exclusion criteria were revisited, and the study sites opened to countries with less clinical routine use of the interventional therapy compared to Germany, The Netherlands, Switzerland, or Italy. The echo core lab was transferred from the United States to Mainz, Germany. Focusing on Greece, Poland, Portugal, Germany, and the Czech Republic, screening and randomization of patients soared to more than 200 patient screenings and more than 160 patient randomizations since December 2015. The COAPT trial is unique because it covers a combined primary endpoint of mortality and hospitalization compared to hospitalization alone.

What are your thoughts on studying the use of mitral devices for tricuspid disease? What are the anatomic challenges or adjustments needed, and is this process of adjustment similar to when aortic valve devices were studied for mitral disease?

Treatment of mitral valve disease is more similar to tricuspid valve disease than aortic valve stenosis, as we are treating regurgitant valves compared to stenotic valves. In mitral valve disease, the leaflets are longer and more mobile, the valve orifice is larger, and the underlying morphologic changes are more diverse than in aortic valve disease. Annular dilation of the mitral valve varies from elliptic to rounded, and the diameter ranges from 33 to 55 mm.

The anatomic challenges are that tricuspid valve disease has been underdiagnosed and undertreated in the past. Imaging is also more challenging in the tricuspid space, as the distance to the esophagus is more pronounced, the valve is angulated, and aortic root sclerosis or calcification can limit imaging access to the valve. Tricuspid leaflets are more fragile, the annulus is softer, and atrioventricular conduction in the triangle of Koch can prevent surgical and interventional approaches to parts of the septal leaflet.

On the other hand, the tricuspid valve is easily accessed using the transvenous approach. There is a paucity of landmarks to the valve from the echocardiogram, and CT imaging technicians need specific training in order to access leaflets, annulus, coronaries, and ventricular muscle in their image acquisition and analysis.

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Which approach do you think will prove to be the optimal concept for percutaneous repair of tricuspid regurgitation?

The best approach will depend on device safety, ease of use, and efficacy to reduce tricuspid regurgitation. In my opinion, annular approaches with flexible rings and certain modifications of leaflet interventions will be the first-line therapy in the next few years. In the rare cases of prolapse, chordal transvenous concepts may enter the market if deemed profitable enough.

What do you believe to be the gold standard imaging protocol before, during, and after transcatheter mitral valve intervention?

I think the gold standard will remain echocardiography including three-dimensional (3D) multiplanar transesophageal images before the procedure to plan the intervention, using fusion images with CT or fluoroscopy during the intervention, and all follow-up exams will rely heavily on echocardiography. We may see a new era and indication for CT in the preprocedural planning phase, as the images are high resolution, it confers less radiation, and the relation of valve structures to vessels, such as the coronary sinus or the circumflex artery, can be visualized. This information can then be used in the cath lab as a 3D overlay to fluoroscopic images. MRI may play a minor role in quantification if the echocardiogram is inconclusive or provides borderline or discrepant information.

Will the transthoracic echocardiographic reference ranges for proximal aortic dimensions gained from the EACVI NORRE study affect procedural approaches, or are they more intended for use as a diagnostic tool?

The EACVI NORRE study was intended to recheck the population basis for normative echocardiographic values in a European context. The study not only includes diameters on two-dimensional data sets, but, in accordance with the 2015 chamber quantification guidelines,[1] it also includes a tool set of volume data sets acquired in 20 European certified echo labs. Similar to the latest and upcoming ACC/AHA update on valvular heart disease for 2017[2] and the upcoming European update on the 2012 valvular heart disease guidelines, the EACVI NORRE study provides evidence and background to rely more on values indexed to patient body size and weight instead of normative absolute values that often ignore specific intervention cutoffs for women or smaller populations. This perfectly aligns to recent awareness that the aortic root should be approached differently depending on presence of fibrous tissue disorders, adult congenital disease, and hypertension, as well as patient sex, regional heritage characteristics, and size.

Are there any other aspects of your clinical practice or research that you are particularly excited about and wish to share with us?

I think that we are experiencing an era of rapid change in valvular and structural heart therapies, as well as in congenital disease treatment strategies, to more minimally invasive approaches driven by an increase in disease prevalence due to longer survival and increased patient age. In the developed areas of the world, this has led to a huge shift of treatment options into transcatheter techniques combined with an industry-driven accelerated speed of medical device innovations. This, in turn, changes the way we can and should train heart specialists, evolving to a more interdisciplinary approach to heart disease that involves new hybrid interventionists using a common toolbox of percutaneous devices rather than solely heart surgeons or cardiologists. This change in training approach has to be accomplished by working in multidisciplinary teams with flat hierarchies and involves knowledge of cardiovascular imaging, wire and catheter skills, as well as vascular and heart tissue access and closure options. The future will be structured interventions with an increase in safety, productivity, a shortened learning curve to conventional techniques, and last but not least, improved patient outcomes in increasingly elderly patients with comorbidities deemed untreatable just a decade ago. ■

1. Lang RM, Badano LP, Mor-Avi V, et al. Recommendations for cardiac chamber quantification by echocardiography in adults: an update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. Eur Heart J Cardiovasc Imaging. 2015;16:233–270.

2. Nishimura RA, Otto CM, Bonow RO, et al. 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines [published online March 10, 2017]. J Am Coll Cardiol.

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