AN INTERVIEW WITH...

Gry Dahle, MD

Dr. Dahle shares her thoughts on the current and emerging technologies for valvular disease, as well as her advice for new surgeons entering the field.

What area of mitral valve disease do you think deserves greater attention and clinical study?

There has been an increasing focus on mitral valve therapies after the release of the COAPT and MITRA-FR studies. However, the bottom line here is that, in daily life, optimal medical treatment (including titration with maximum dosage of angiotensin-converting enzyme inhibitors, β-blockers, diuretics, and aldosterone inhibitors) is of great importance.

When deciding on a treatment approach, the possibility of combined catheter-based treatments should be explored. At present, these therapies are seldom combined because of the long procedural time, large amount of contrast needed, and long radiation exposure time. However, the most important factor is reimbursement; if two devices are used in the same procedure, only one is reimbursed, so the procedure has to be staged, which also may be a good clinical approach.

The treatment of mitral annular calcification (MAC) is difficult during open surgery as well as in catheter-based treatment. Transcatheter aortic valve implantation (TAVI) devices have been used both in hybrid procedures and in catheter-only procedures, but the mortality rate is high. The problem is mainly left ventricular outflow tract obstruction, but this can be prevented by removing the anterior leaflet, performing septal ablation, and excluding acute angles.

In addition, we need to be more aggressive in the treatment of tricuspid annular dilatation and regurgitation concomitant to mitral valve treatment, as redo procedures after both surgery and catheter-based treatment are associated with higher morbidity and mortality. The guidelines are vague and further studies are warranted.

Furthermore, there are questions of valve thrombosis and anticoagulation in terms of their clinical relevance and treatment decisions. It is also unknown whether valve durability may be shorter in the mitral anatomy compared to the aortic anatomy. In our experience, we had one valve thrombosis (resistant to anticoagulation) and one valve degeneration after valve-in-ring procedures. Both of these were successfully treated with "valve-in-valve-in-ring" approaches.

As a principal investigator for the Expanded Clinical Study of the Tendyne Mitral Valve System trial, can you provide some background on the trial's design and its current status?

The objective of this study is to evaluate the performance and safety of the Tendyne mitral valve system (Abbott Structural Heart) in the treatment of severe, symptomatic mitral regurgitation for patients in whom a transcatheter approach is preferred over open heart surgery. The system includes a self-expanding trileaflet porcine pericardium bioprosthesis consisting of an inner frame that comes in two sizes and an outer frame that is available in multiple sizes to cover a broad range of annular dimensions. It has a transapical delivery system, is repositionable and retrievable, and is anchored with a tether to the apex. To date, more than 170 patients worldwide have been treated with the Tendyne system.

The study is currently enrolling new patients in Europe, Australia, and in the United States. The study will enroll up to 350 patients and follow them for up to 5 years to collect long-term safety and performance data. The 30-day results for the first 30 patients were published in the *Journal of the American College of Cardiology* (*JACC*) in 2017,[1] and the 1-year outcomes from the first 100 patients treated in the Tendyne Expanded clinical study were recently submitted and accepted for publication in *JACC*.

At the beginning of this year, our center also published an article to discuss the screening process and the treatment results of the excluded and included patients.[2] In our experience, the treated patients are doing very well and the procedure proved to be quick and easy. Our longest follow-up is 3 years for two patients.

The Tendyne system also has been shown to be suitable for treating MAC, and there is an ongoing study in the United States, with Drs. Paul Sorajja and Vinod Thourani serving as principal investigators. Additionally, the SUMMIT trial is ongoing in the United States and is randomizing patients to either the Tendyne device or surgical mitral valve repair.

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Of the challenges that remain in refining TAVI devices, which do you think is the top priority or might they all be addressed with concurrent system-wide improvements?

These challenges, including paravalvular leak (PVL), stroke risk, durability, and the need for new pacemaker implantation, are becoming more important as TAVI is being performed in younger patients. Ventricular pacing will sooner or later induce heart failure. In older patients, this is not of great importance, but if pacing continues for decades, the patient may develop heart failure. However, there is still the balance between the need for a new pacemaker and PVL—less PVL causes more pacemaker use—and so the perfect TAVI device is not yet on the market. In addition, there is the challenge of prosthesis-patient mismatch (PPM). As valve-in-valve procedures become more common, this has to be a focus. If PPM is already present, it will become even more pronounced with a valve-in-valve procedure and affect survival.

With respect to stroke, the number of patients experiencing stroke seems to be decreasing even though embolic protection devices are not increasingly used. Regarding the durability of transcatheter valves, we do not yet have consistent clinical data to determine this. Degeneration tends to become a problem after 7 to 10 years for surgical valves, but there are no studies older than 6 years for follow-up of TAVI valves. However, the definition of degeneration is debatable, and it will also be challenging to directly compare surgical and catheter valves.[3]

Do you have any concerns with making TAVI procedures available to lower-risk patients? Do you believe that TAVI should eventually be an option to all patients who require valve replacement?

The previously mentioned concerns apply more to TAVI in younger patients. Due to concerns related to durability, younger patients should undergo surgical mechanical valve replacement. Even though valve-in-valve techniques may be a possibility, there are some concerns, such as size and PPM and the possibility of coronary interventions after a valve-in-valve procedure. Transfemoral TAVI in older, low-risk patients may offer better outcomes over a surgical approach due to the shorter recovery time and hospital stay.

Still, there are some patients who would benefit from surgery, such as those with bicuspid valves and aortic regurgitation. For bicuspid valves, there are technical challenges inherent in the oval-shaped ostium, which also often have an uneven distribution of calcium, for sizing and positioning. Some patients with aortic regurgitation can have surgical repair instead of replacement, which is an advantage because the patient's own valve can be fixed as opposed to replaced, although this takes precision and a perfect repair.

Finally, the economic aspect is also a concern. TAVI devices are much more expensive than surgical valves, and this extra expense may be a burden on society.

Do you have any tips for optimal imaging techniques or best practices for determining patient selection for transcatheter valve interventions?

Currently, there are many new imaging techniques on the market, and most of them need to be tested and evaluated to determine best practices. Still, CT reconstruction is the best method to determine anatomic suitability, and echocardiography is the best method for functional assessment. There are many other sophisticated tools available to refine and improve these methods. For instance, cinematic rendering from CT provides photorealistic graphics of the anatomy and hence more details for better planning.

CT reconstruction can be used for three-dimensional (3D) printing and also for a holographic view. The holography is a kind of "paperless/rubberless" version of the 3D printout. These methods are very important, especially for the evaluation of abnormal anatomy/congenital defects. The HoloLens tool (Microsoft) allows the opportunity to overlay the different reconstructions. The fusion imaging of CT and echo/echo and fluoroscopy are also useful tools.

Because there are so many advanced imaging tools and techniques, in the future there may be a need for multimodal imaging specialists who can synthesize imaging information and organize it into a practical clinical perspective.

Which area of cardiovascular technology are you most excited about in terms of new innovations in the pipeline?

In the era of cardiovascular technology, the new imaging tools and the combination of valve and heart failure interventions have great potential and are very exciting. With new transcatheter treatments, the elimination of valve regurgitation or stenosis may improve heart function and limit heart failure.

Intervention for tricuspid valve regurgitation and the significance of right heart failure and survival are subjects of discussion, but evidence and conclusions are currently lacking. There is need for trials, guidelines, and criteria from the Valve Academic Research Consortium for tricuspid valves.

The inclusion of heart failure sessions in any heart valve meeting is very fruitful and interesting, will provide new information, and is also valuable for patients. It will be interesting to see if TAVI or mitral/tricuspid intervention is bet-

ter when performed in advance, instead of concomitantly, during ventricular assist device implantation.

What do you think is the best venue/approach to educating cardiothoracic surgeons on new techniques and technology? What is most lacking in the current approach?

Simulators for catheter valve treatment and for surgery on 3D-printed heart models are getting better and more realistic. They are valuable when training for new procedures.

Working in a heart team can have advantages as far as learning new techniques and technologies. New techniques are less invasive, and technology aims to facilitate it. Surgeons and cardiologists should work together to develop this further. Currently, integration between specialties is lacking, and among colleges, there is still a protective attitude with respect to their own discipline. In the future, there likely will be a need for new specialties, such as "interventional surgeon" or "imaging interventionalist."

What advice would you offer those who are just entering the field of cardiothoracic surgery?

First, they have to reflect on the fact that open surgery today will not be the surgery of tomorrow. Fewer surgeries are performed under direct vision. I recommend that they be open-minded to new innovations and be prepared that surgery is becoming less invasive in one way but very complex in another. Still, surgery will be needed in cases when catheter-based treatment fails, as well as for endocarditis and transplantation, which are often complex procedures.

On the other hand, it is important to join together with the cardiologists to learn catheter-based treatment techniques and be aware of imaging modalities as tools for planning and during the procedure. You have to learn to interpret echocardiogram results and perform CT reconstructions. For a procedure, always be prepared and have a "plan B" if the initial plan fails. Ask for help from more experienced surgeons and listen to them. Always talk with patients and their relatives to gain information and achieve their goals. Remember, we are treating human beings, and it is not only a technical procedure we are performing to become the best in our discipline. ■

1. Muller DWM, Farivar RS, Jansz P, et al. Transcatheter mitral valve replacement for patients with symptomatic mitral regurgitation; a global feasibility trial. J Am Coll Cardiol. 2017;69:381-391.
2. Dahle G, Helle-Valle T, Beitnes JO, et al. Single-centre first experience with transapical transcatheter mitral valve replacement with an apical tether: factors influencing screening outcomes [published online January 2, 2019]. Interact Cardiovasc Thorac Surg.
3. Dvir D, Bourguignon T, Otto CM, et al. Standardized definition of structural valve degeneration for surgical and transcatheter bioprosthetic aortic valves. Circulation. 2018;137:388-399.

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