Simulation Training and Medicine

One physician's experience with simulation to educate physicians on new devices and therapies.

BY PROFESSOR ALAIN CRIBIER, MD

Simulation training has been a training tool in health care since the 1960s but has only recently reached a level of technical advancement and industry acceptance that allows it to be a practical, effective, and very influential tool for advanced procedural and medical product training. Just 5 years ago, simulation was emerging only for coronary and simple peripheral procedures. Now, physicians and procedural teams are trained in patient management and procedural skills for complex structural heart therapies and are having a clear impact on the therapy coming to many new centers across Europe, Canada, and the US, with improved clinical success and reduced complication rates.

The foundation for this advanced therapy must start with the basics, and simulation offers a wonderful ability to integrate basic skills within complex learning algorithms. There is a continuum in learning that is not dissimilar to that of performance. Simulation can meet a practitioner where they are on that continuum and create a unique experiential learning event. Simulation is especially effective in a well-designed and comprehensive training program that combines simulation-based training with didactic lectures, case studies, case observation, and expert teachers. We are using this holistic approach at our facility in Rouen (Hospital Charles Nicolle, University of Rouen, France).

SIMULATION TRAINING AT UNIVERSITY OF ROUEN

When I was initially working on transcatheter heart valve replacement in 2002, I did not think, "How are we going to train physicians to do this procedure?" as much as "How can this therapy work?" I believe that in many instances, training for interventional procedures based on complex device delivery is not a priority, especially knowing that there will be many iterations and improvements; however, the ability to widely train physicians on complex medical devices is very important and should be considered early in the development cycle. The transcatheter heart valve replacement procedure has evolved from the antegrade approach (Figure 1) to a retrograde approach (Figure 2), and, although still challenging, it has simplified the overall procedure and brings more favorable outcomes (Figure 3).

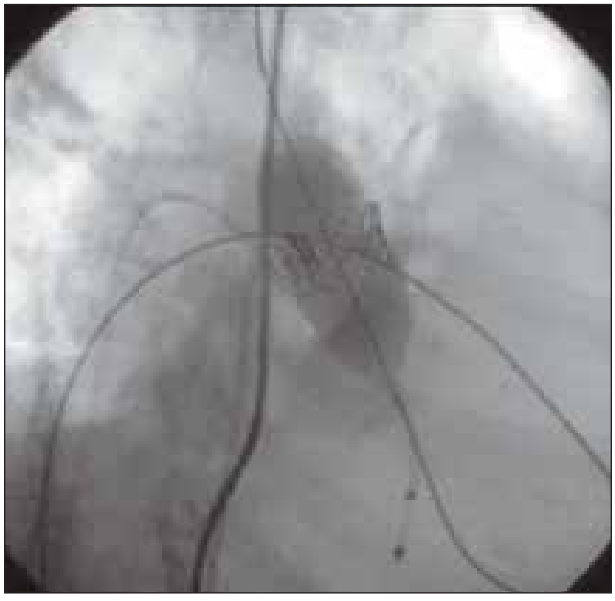

Figure 1. Antegrade transseptal approach.

Procedural success begins with careful patient selection, which needs to be included in any training platform, especially simulation. High-risk surgical valve patients come with complex anatomic challenges, as well as severe comorbidities, which have to be considered in any treatment approach. The physician's ability to understand these challenges and anticipate problems must be part of the process. There is a very steep learning curve through which anything learned should be available and transferable to other physicians and the teams who will be performing the procedure. The ability to not only understand the learning curve but also to experience it hands-on is most beneficial to physicians who undergo training.

This concept is particularly important with a new therapy, such as the Edwards Sapien Transcatheter Heart Valve (THV,

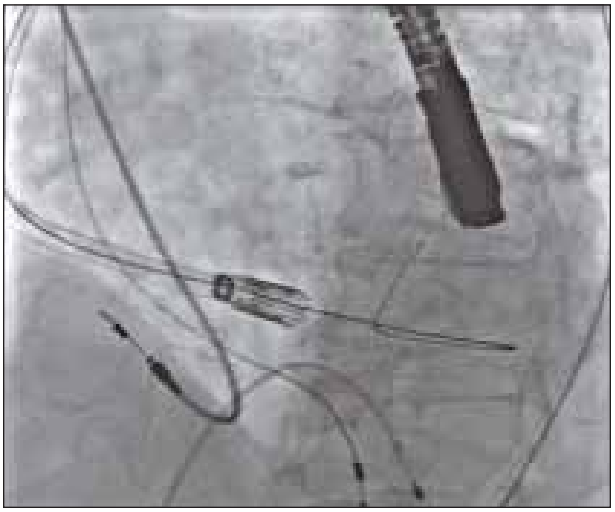

Figure 2. Retrograde transfemoral approach.

Figure 3. THV after implantation.

Edwards Lifesciences, Irvine, CA), because two physician specialties are being trained to deliver a device with completely different approaches: transfemoral and transapical. There is a significant learning curve for both cardiologists and cardiac surgeons. The aortic valve is very familiar to the cardiac surgeon, and the performance of a bioprosthesis in terms of placement and impact on the native valve is very valuable for the cardiologist to learn and understand in this high-risk patient population. For the cardiac surgeon who may be missing some of the basic angiography techniques and interventional skills, simulation has been a wonderful platform to help teach those skills and, specifically, the skills needed for transcatheter heart valve therapy. Potentially more valuable is the experience of working together to share information, discuss technical approaches, and move toward a good clinical outcome through simulation.

THE THV TRAINING PROGRAM

If we briefly walk through the THV training program, I believe we can show a very effective methodology of using simulation for training. The initial step is to provide a knowledge base to trainees. This starts with a precourse Web training program that covers general aspects of the procedure, clinical trial information, and history, as well as patient selection criteria, complications and management, and some level of interactive experience on both the product and the procedure. As a proctor, I expect that trainees review the THV Web site to understand some basic information on the procedure and the device. This allows participants to ask well-directed questions and engage in the dialogue of the procedure.

The training course is a 2-day course for procedural teams that includes cardiothoracic surgeons and interventional cardiologists, as well as anesthesiologists, echocardiographers, and nurses. The course includes a detailed presentation on the procedure, including transapical (Figure 4) and transfemoral approaches, a review of clinical outcomes, and case studies. It also includes live-case demonstration of the transfemoral and transapical approaches, with video transmission from the catheterization laboratory and the cardiac surgery operating room. There is a product demonstration by the device manufacturer that includes a hands-on session so that operators can become familiar with the actual equipment. The groups then split into their respective specialties and begin the simulation workshop. A patient scenario is presented, along with diagnostic data, which allows the trainee to work through all criteria necessary to proper patient selection.

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For transfemoral patients, iliofemoral anatomy must be correctly assessed and considered appropriate before scheduling the procedure (Figure 5). Small, diseased iliac arteries are exclusionary for transfemoral because of the current large delivery systems. Many of the early challenges were related to peripheral complications and can now be avoided by diligent peripheral assessment. For cardiac surgeons and nonperipheral cardiologists, there is the opportunity to offer simulation experiences in iliofemoral angiographic techniques and even intervention. This can be very valuable for procedural teams who will be assessing patients together, allowing better dialogue to determine the best therapy for this high-risk patient population.

Figure 4. Transapical approach.

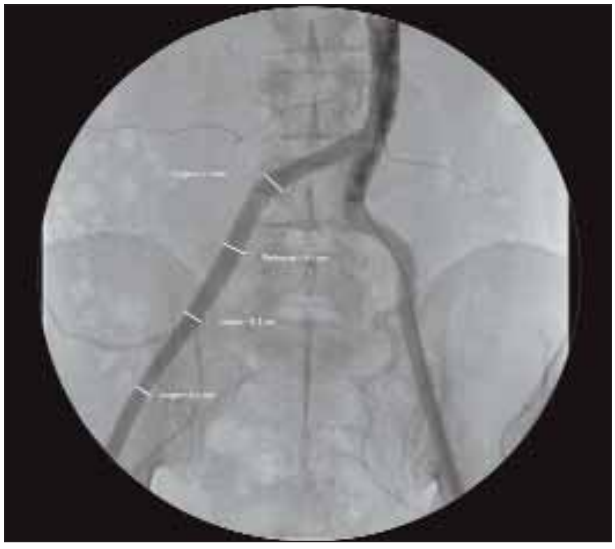

Figure 5. Iliofemoral assessment in simulation.

Echocardiographic imaging and aortography are also considered before the procedure to determine device sizing and assess other exclusion criteria. Once the patient has been assessed and a discussion has occurred, physicians work together in different roles to perform a complete procedure, including angiography, aortic valve crossing, balloon aortic valvuloplasty, and device implantation. Valve positioning and deployment are some of the most intense moments of the training, and I often witness trainees react as I would expect in a real procedure. This is so important to experience, especially with a suboptimal placement, because it allows one to fully grasp the importance of communication and device handling in the complete environment of machine sounds and voices and second guesses. A mistake encountered in simulation can be remembered as one to be avoided in a real procedure.

In simulation, complications are managed, and operators get a true feel for the procedure, how the equipment looks and performs, and what a good outcome or a suboptimal outcome looks like. Repetition is a key concept for this training, especially to synchronize operators who have different functions to perform simultaneously. Simulation is very effective for repetition because actions can be practiced multiple times in a very safe and cost-effective manner. Performance metrics can be reviewed after the simulation and discussed in an open forum that allows trainees to then share experiences rather than discuss what was seen. This is an added level of interaction that lecture and case studies cannot provide. Often, both the surgeons and the cardiologists "swap" roles and perform both the transapical and transfemoral simulations with the intent of understanding the unique challenges that are faced by respective operators. As a procedural team, everyone is involved in cases and various levels, and both specialties often work together in the same facility. The course then moves through some complication studies and some materials on proper hybrid lab set-up and team-building activities. Our courses often incorporate live-case observation from our interventional suite so that attendees get one more level of experience with the training.

During the simulation and throughout the course, expert proctors participate and offer experiential tips and instruction that encourages thinking and questions. One unique aspect of this program is the involvement of clinical educators who have worked as nurses and technologists in interventional labs. They have a large amount of knowledge that is constantly being accessed by trainees. They also ensure the smooth operation of the simulator in a way that makes it more transparent and allows the trainees to really experience the product and procedural aspects of the training experience.

As physicians practice complex procedures through simulation, they are contributing to a database of objective data that are collected and can then be used for many purposes. Performance metrics play an important role in the contribution of tangible data to companies, such as those that manufacture medical devices. These data can be stored and used for evaluation of procedural understanding in different populations of physicians, as well as how perceived knowledge and understanding is translated into practical hands-on knowledge. Important to each individual is the timely feedback of his or her performance. Metrics can be used as a lead into thoughtful discussion at the simulator that can point out common practices that need to be included in valve implantation, as well as practices that need to be avoided.

We can expand this type of program to include catheterization lab staff training and integrate it into a general training program for new staff, and advanced training for staff, that is going to be integral to THV procedures. Operative nursing staff can also be trained on basic techniques as well as THV-specific skills that help the team perform well.

There is no patient safety barrier to allowing staff, medical students, device company engineers, sales force, and even patients and their families to experience the procedure via simulation. As we go forward, each group will require reconfiguration of the training experience to meet their specific goals.

EFFECT ON LEARNING

Simulation has had a positive impact on the learning curve for new procedures. The education in Rouen is successful because of the thought and delivery of a simulation program that consists of all factors that occur in learning. As the practice of simulation moves forward, the benefits will likely be recognized more broadly.

This valuable tool can be used as a way to introduce and educate physicians in new practices in medicine. As the medical device industry looks to new ways of introducing products and ensuring their correct use, simulation is the road they will most likely take, offering the ability to guarantee understanding of correct use and appropriate patient selection as well as introducing widely new concepts in medicine. Standardization of training is a concept that has been difficult to implement in the "art" of medicine, but for complex procedures such as transcatheter heart valve replacement, it will greatly affect success and define a world-class training program. ■

Professor Alain Cribier, MD, is Chief of Cardiology at Hospital Charles Nicolle, University Hospital of Rouen, France. He is Professor of Medicine, former president of the French Society of Interventional Cardiology, and has been a pioneer in the field of aortic and mitral valvuloplasty, performing the first world case of balloon aortic valvuloplasty in 1985, the first world case of metallic commissurotomy for mitral stenosis in 1995, and the first world case of percutaneous aortic valve replacement in April 2002. Professor Cribier is currently serving as a physician proctor in the Edwards Lifesciences THV training program in Europe for the Edwards Sapien Valve. Together with Edwards, he has established one of several simulation training centers for the THV implantation program using the SimSuite technology from Medical Simulation Corporation in Denver, Colorado. The training sessions in Rouen are held by himself and the members of his team from the Cardiology Department (Professor Eltchaninoff and Dr. Tron), as well as the cardiac surgeons of the institution (Professor Bessou and Dr. Litzler). Professor Cribier may be reached at alain.cribier@chu-rouen.fr.