AN INTERVIEW WITH...

Nicolas Van Mieghem, MD, PhD, FESC, FACC

Professor Van Mieghem discusses cardiovascular clinical trials in the COVID-19 era, cerebral embolic protection, three-dimensional modeling, and more.



Your research interests span a wide variety of topics in the percutaneous coronary intervention (PCI) and structural heart realms. What area of interventional cardiology are you most passionate about and why?

I'm passionate about interventional cardiology in general! Andreas Gruentzig, MD, is one of my ultimate heroes! It's amazing how he pioneered this field from scratch. My research focuses are (1) advances in transcatheter aortic valve replacement (TAVR), covering new indications and accessories to improve safety (eg, cerebral embolic protection, large-bore closure devices); (2) mechanical circulatory support (MCS); and (3) treatment of calcified coronary lesions.

As a Principal Investigator for several ongoing clinical trials, how are you managing your non-COVID-19—related cardiovascular clinical trials amid the pandemic?

COVID-19 created some major challenges, especially in the early stages of the pandemic. Trial coordinators are working from home, patients are no longer showing up for follow-up visits on-site, and device delivery to the sites as well as on-site product support can be problematic. Telemedicine can fill in the gap of on-site follow-ups, and we are exploring virtual/online product support, proctoring, etc. At this point, most trials are proceeding back to "normal."

You were an investigator of the WIN-TAVI registry evaluating clinical outcomes of TAVR in women, which has seen several follow-up analyses—the prevalence of patient-prosthesis mismatch, the impact of diabetes mellitus or chronic kidney disease, and the impact of discharge location just to name a few. What are the most important lessons you learned

about female sex-specific outcomes in women undergoing TAVR?

The major insights are that TAVR works very well in females, and the long-term outcome is excellent. The procedure comes with a risk for access site bleedings and complications (more so than with males); however, device iterations, in terms of device profile and dedicated closure devices, may have resulted in safer procedures. A recent subanalysis of the randomized SURTAVI trial also pointed to excellent results with TAVR and even superior improvement in quality of life early on and functional performance (even out to 2 years)!¹

Recent years have seen progress made toward demonstrating the benefit of cerebral embolic protection in patients undergoing TAVR. What do you think needs to happen to reach a consensus on this?

I've been a firm believer in the mechanistic concept of filter-based embolic protection for 8 years, and cerebral embolic protection has been the standard in my practice for the last 5 years. The frequency, kind, and amount of debris that we have been seeing (macroscopically or under the microscope) is compelling. I cannot understand how debris entering the brain can be an equivocal thing. If we can prevent this, we should. That said, we will need the data from the PROTECTED TAVR randomized trial on 3,000 patients to help convince the field—on the condition that clinical benefit will be demonstrated.

Although there is still work to be done, we've seen the benefit of multidetector CT-derived, three-dimensional (3D) modeling and printing in transcatheter mitral valve replacement. Where do you want to see this technology applied and studied next?

3D modeling is a fascinating pathway to help plan complex structural heart interventions. I see immediate

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implications for transcatheter mitral valve replacement and also believe left atrial appendage closure could benefit from this. It is eye-opening how much one can learn from 3D-printed models and computer simulations of implantations. Technology is absolutely in sync with the year 2020!

As someone very involved in the development of and research on MCS devices, can you briefly summarize your decision-making process for whether a patient needs MCS and what type of support is right for them?

First and foremost, MCS requires meticulous access site management. We pay a lot of attention to this, and in my staff, all interventionalists who use MCS are trained to obtain safe large-bore access. The moment safe access management can be guaranteed on an institutional level, the option for MCS becomes relevant. I especially consider MCS in high-risk PCIs as I embark on cases with a combination of poor left ventricular function and anticipated complex coronary interventions. I'd then use Impella CP (Abiomed, Inc.) or the PulseCath iVAC2L (Terumo Europe). In preshock patients, I still consider intra-aortic balloon pump (IABP) especially in the intensive care unit or Impella in the cath lab. In specific cases, extracorporeal membrane oxygenation is the only proper option; in those instances, I always combine with IABP to vent the left ventricle.

What were some highlights from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) proposed core curriculum for PCI,² for which you were on the committee? Why is it important to have this homogeneous education?

The EAPCI curriculum is a vast document that creates structure and harmonization. This becomes increasingly important to create an equal/level playing field for all interventionalists in Europe. An important notion was

the separation between standard and advanced training centers. We need to be clear who will and should enter advanced training.

How do you find a balance between your professional life—medical education, numerous clinical trials, published research, and work at the medical center—with your personal life? Do you have any advice for those new to interventional cardiology on maintaining that balance?

I'm not sure that I'm the best person to ask! Clearly, the field of interventional cardiology is my passion. The clinical work especially is absolutely fascinating. The immediate impact on patients' lives is just so rewarding on a personal level. But I also enjoy the academic part. Long story short, I decided to focus on my career and find the people who could understand the lifestyle and see the passion. It's all about understanding. Life is an amazing journey!

- Van Mieghem NM, Reardon MJ, Yakubov SJ, et al. Clinical outcomes of TAVI or SAVR in men and women with aortic stenosis at intermediate operative risk: a post hoc analysis of the randomized SURTAVI trial. EuroIntervention. Published online July 21, 2020. doi: 10.4244/EIJ-D-20-00303
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