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Contemporary structural heart disease registries: when professional networking meets clinical research

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In 2010, we performed our first transcatheter aortic valve implantation (TAVI) within a failed surgical bioprosthetic valve. We treated an older woman who suffered from a critical aortic stenosis within a Mitroflow (21 mm) surgical bioprosthesis (Sorin Group, Saluggia, Italy) and was in our intensive cardiac care unit (CCU) with impending cardiogenic shock. Earlier that day, we had performed three successful TAVIs to treat native stenotic aortic valves. I asked my proctor, Jean-Claude Laborde, to come with me to the CCU to consult on the case. The patient's haemodynamics were deteriorating rapidly and, despite her low systemic blood pressure, her gradients across the aortic bioprosthesis were 90/60 mmHg on echo-Doppler examination. J.C. Laborde examined the patient and then said to me, "Ran, we have to treat her now, this is her only chance to survive". We called the family *ad hoc* and described the valve-in-valve TAVI procedure. We then obtained informed consent and rushed the patient to the catheterisation laboratory to perform our first TAVI valve-in-valve procedure under extreme unplanned circumstances.

The patient underwent full anaesthesia. We used transoesophageal echo guidance and were able to obtain femoral access without any difficulty. We implanted the "classic" CoreValve® (26 mm) (Medtronic, Minneapolis, MN, USA) within the Mitroflow bioprosthesis with immediate favourable results. Soon after implantation of the new valve, the patient's systemic blood pressure surged dramatically, her left ventricular function improved, and the residual gradient dropped to 26/12 mmHg based on both catheter-based and Doppler measurements. The patient was awake after 30 minutes without any difficulty, and the subsequent hospitalisation course was uneventful. I was stunned and excited by the procedural and clinical results.

During the debrief we had to summarise four successful TAVI procedures that day, I proposed to the team that we should run an international registry to collect numerous valve-in-valve TAVI cases. I thought it would be of great interest to share collective experiences about this innovative and extremely effective procedure. I asked my fellow, Danny Dvir, to assist me with the

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endeavour. In collaboration with J.C. Laborde and our mutual professional networks, we drafted and distributed a "Call for Registry" e-mail with the aim of collecting systematic data on the valve-in-valve TAVI procedure, inviting multiple international centres to participate in our self-reported registry. For those who responded favourably, we also attached a case report form (CRF) that could be used to provide the requested data detailing the procedure.

This project later evolved into the global Valve-in-Valve International Database (VIVID). Thus, it started as an unsponsored, investigator-driven project with its success based on the willingness of wide-reaching colleagues to collaborate and contribute accurate data to this field of research. Since then, the VIVID registry has evolved and flourished under the leadership and enthusiastic attitude of D. Dvir and has become an important source for multiple investigations and publications that have shaped the field of valve-in-valve interventions. By no means has the registry replaced the need for a prospective clinical trial. Nonetheless, clinical data from prospective registries appeared a few years later; they were restricted to patient populations selected according to carefully designed protocols, which do not necessarily represent the collective "all-comers" experience. To the best of my knowledge, the VIVID project has initiated and perpetuated a movement of additional investigator-driven registries in the field of TAVI. These collective surveys aim to explore unique features of this field. Over the last decade, numerous registries have addressed important questions associated with TAVI, such as the manifestation of stroke and the effect of embolic protection devices, vascular complications, procedural haemorrhage, renal failure (pre/post interventions), fever and infectious disorders, sex-related TAVI issues, the impact of left ventricular function, need for mechanical support during interventions, risk stratification based on various risk scores (prognostication and futility measures), coronary occlusion, TAVI associated with coronary artery disease, oncology-related TAVI outcomes, temporal trends and comparative analyses between old and new devices, electrical conduction abnormalities and/or need for pacemaker implantation, paravalvular regurgitation, multivalvular disorders, mode of anaesthesia, adjunct interventions (e.g., BASILICA and bioprosthetic ring fracture manoeuvres), transcaval approach to TAVI, valve durability, TAVI in TAVI, and procedure-related delirium and cognition, among others. Our group has either initiated or participated in some 20 multicentre registries since VIVID, all of which have yielded important scientific information that was presented at cardiology meetings and transformed into peer review publications in the medical literature. Multiple centres have experienced similar capabilities. I am not aware of a similar field of cardiovascular activity in which a procedure has produced such a plethora of collective investigator-driven and self-reported original data in such a short period of time. This scientific activity has presumably had an impact on other fields of structural heart intervention with multiple ongoing registries being created in recent years.

One has to consider the pros and cons of such self-derived data registries. In general, clinical data registries record information about patients' health status and the care they receive over time. These registries typically focus on patients who share common characteristics (e.g., aortic stenosis, mitral insufficiency, etc.), allowing caregivers to acknowledge available treatments and how patients with different characteristics respond to certain treatments. Different types of registry track specific aspects of care and/or associated procedural complications. A registry may focus on a disease or condition, a procedure (e.g., TAVI), or a specific device. The registry defines a patient population, then recruits physicians and/or other healthcare professionals to submit data on a representative sample of these patients. Data are used in treatment analyses (e.g., studying the attributes of the population in the registry and finding patterns) and can help to identify particular outcomes. As all of the factors that might have an impact on outcomes are not necessarily known at the time of data collection, the data are stored and can be revisited to evaluate previously unrecognised associations. Data should be collected via secure online portals or electronic health record (EHR) systems. As data are entered into the clinical data registry, quality checks should be performed to ensure that the data are correct and complete. If information is missing or data are outside the expected range, registry staff ask the submitting team to review and verify the data. The completeness of data collection is a key factor in assuring the reliability of the overall process. In reality and practice, registries help to improve healthcare quality and safety. Registries are used to compare the effectiveness of different treatments, evaluate different approaches to a procedure, and monitor the safety of implanted devices. In some countries, information from registries (mostly comprehensive national queries) is increasingly employed to ensure that payment is adjusted based on the quality of care provided, or to give patients the information they need to make better choices. Despite the large number of articles published using data derived from TAVI registries, the quality control processes are relatively limited with uncertain rigour about information collection, data analysis, and/or proper evaluation of outcome measures. It is pretty much "in the eye of the beholder", and a process derived from mutual trust and respect. Moreover, the impact of the TAVI registries on the process of reciprocated learning and/or improving procedural outcomes has not always been clear. In other fields of medicine, those who have evaluated this impact have mostly found that registries improve healthcare processes and outcomes. Thus, there is no reason to believe that this is not the case with TAVI or other structural heart interventions. No studies have evaluated the economic impact of registries on an intervention, either in TAVI or in other cardiovascular procedures.

In summary, since the VIVID registry was created, there has been much activity in the field of collaborative investigator-driven data registries for TAVI and other structural heart disease interventions, with multiple clinical queries being addressed and answered. Since structural heart interventions are a "moving target" in terms of

procedural techniques, therapeutic indications and/or patient characteristics, one should expect this trend to carry on and even grow. Numerous presentations and publications continue to appear at meetings and in the medical literature to provide renewed "real-life" data on the quality of care, as well as better insight into procedural complications and how to improve procedural results. These registries also provide an opportunity to evaluate rare complications, unusual indications and/or subgroups of patients that are not well studied by the industry-sponsored trials. Importantly, the TAVI era continues to show the power of professional collaboration driven by motivation to share clinical experiences, and by the friendship and trust that exist among interventional cardiologists around the world. This is a fascinating phenomenon and a conjunction of professional networking with clinical research aiming to improve the outcomes of patients treated for valvular/structural heart diseases.

Conflict of interest statement

The author has no conflicts of interest to declare.