The need for a Spanish registry of interventional procedures to treat congenital heart disease and standards for center accreditation

La necesidad de un registro español de intervencionismo en cardiopatías congénitas y de estándares para la capacitación de centros

Ángel Sánchez-Recalde, a, * and Federico Gutiérrez-Larraya b

a Servicio de Cardiología, Hospital Universitario Ramón y Cajal, Madrid, Spain
b Servicio de Cardología Pediátrica, Hospital Universitario La Paz, Madrid, Spain

Over the last 3 decades, the percutaneous treatment of congenital heart diseases has made significant progress. Currently, it is the therapy of choice to treat many of these diseases like atrioventricular septal defects, pulmonary valve stenosis or coarctation of the aorta. Multiple procedures throughout the life of a patient are required to treat complex heart disease like stenting and, more recently, percutaneous valves, which have become additional alternatives to surgery.

Since 1990, cath lab activity is regulated in the registries published by the Interventional Cardiology Association of the Spanish Society of Cardiology (ACI-SEC). In the annual publications of these registries there is a small section dedicated to congenital heart disease in the adult population with details on the activity performed, but without an in-depth analysis of the outcomes, complications or mortality.

The ACI-SEC and the Spanish Society of Pediatric Cardiology and Congenital Heart Disease Working Group on Hemodynamics have joined forces—for the first time in our country—to conduct a registry of the procedures performed in patients of all ages with congenital heart disease since the fetal stage until the adult age with the collaboration of pediatric and adult cardiologists. The Spanish Society of Cardiovascular and Endovascular Surgery has recently published a registry of surgical procedures performed in patients with congenital heart disease from 2019, and retrospectively, of the past 8 years. Therefore, we should mention that, to this date, in Spain, we have surgical and percutaneous activity registries in the specific field of congenital heart disease.

In the first official report from the Spanish Cardiac Catheterization in Congenital Heart Diseases Registry—recently published in REC: Interventional Cardiology—Ballesteros Tejerizo et al. reported the activity of 16 public centers, 7 of which have exclusive dedication to pediatric patients in an audited voluntary registry through an online database. The number of participant centers can be representative of pediatric activity. However, this seems like a very low number of hospitals to be representative enough of the activity developed in adult congenital heart disease. As a matter of fact, by 2014, there were already 24 PCI-capable centers with specialized consultations on the management of congenital heart diseases. Also, other centers perform interventional procedures to treat simple congenital heart disease like interatrial shunt and patent foramen ovale closures without specialized consultations. These aspects can explain the huge difference seen between the ACI-SEC national registry that reported a total of 1341 interventional procedures performed in the adult population compared to the 367 procedures reported in this registry. This low representativity of interventional procedures in adult patients should be included in future registries to get an actual snapshot of the activity performed in this field.

The higher rate of almost 5% reported in the activity performed in the management of congenital heart disease in 2000—the pandemic year—compared to 2019 is not easy to explain either though fewer hospitals (2) participated that year. This contrasts with other registries—like the Italian one—where 6 out of the 11 participant centers saw how their activity dropped over 50%, especially among adults and teenagers. Also, during the pandemic, patients with congenital heart disease were a susceptible population with a higher morbidity and mortality risk due to appointment cancellations, and delays in the diagnosis and treatment of complications.

Another significant and debatable aspect is the definition of congenital heart disease included in the registry. The patent foramen ovale can be present in over 25% of the general population and has become part of the interventional procedures performed to treat congenital heart disease. In fact, it is the most prevalent one among the adult population. However, interventional procedures to treat bicuspid aortic valve—considered the most common congenital heart disease and present in 1% to 2% of the general population—was not included in this registry. Although valve disease following calcification often occurs at a younger age compared to the tricuspid aortic valve—at around 50 to 60 years old—current registries show that transcatheter aortic valve implantation is performed in 4% to 5% of the patients with bicuspid aortic valve. Also, bearing in mind that 4241 percutaneous aortic valves were implanted in Spain, it somehow seems logical to agree that nearly 190 were implanted in the bicuspid aortic valve, but this figure was never reported in this registry.

* Corresponding author.
E-mail address: asrecalde@hotmail.com (A. Sánchez-Recalde).

Online: 21-03-2022.
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The pulmonary angioplasty section includes interventional procedures on pulmonary branches, the native right ventricular outflow tract, and prosthetic valve conduits. These are different procedures regarding complexity and potential complication, which is why they should be included in separate sections.

We should mention the low rates of serious complications (2%), and mortality (0.1%) reported, which are similar to the ones reported by the best international registries. The exception to this was interventricular shunt closure with a high rate of complications reported—over 10%—which emphasizes the technical difficulty of this procedure.

The availability of a national registry on pediatric percutaneous procedures and adult congenital procedures with a prospective database is essential for patients, and their families. Also, for doctors who treat and advice patients on the risks and outcomes of a given procedure, and for interventional cardiologists to improve their clinical practice. It allows us to analyze results and draw comparisons among hospitals, autonomous communities, and even countries to eventually implement process management upgrades.

Also, this is closely associated with the need for establishing the optimal conditions to perform percutaneous procedures to treat congenital heart disease, and with the accreditation of both centers and interventional cardiologists. A consensus document was drafted on the need to establish the infrastructure standards and experience that both centers and interventional cardiologists should have by the different working groups and associations on pediatric and adult congenital heart disease, and the European Society of Cardiology. Two different levels of centers were established based on the number of procedures performed each year. Therefore, in level 1 centers, the lead operator should perform, at least, 70 procedures with, at least, 10 percutaneous valve implantations, 10 angioplasties, and stenting to treat coarctations of the aorta, pulmonary arteries, surgical conduits or baffles (for a total of 10 in any of these areas). Also, the second operator should perform ≥ 30 procedures (over 100 in 1 year). Level 2 centers would need to perform over 60 procedures each year. Although these figures can seem arbitrary, it is essential to perform a high volume of procedures per center, and have onsite cardiac surgery teams expert in the management of congenital heart disease to solve potential and emergency complications that may arise. Heart teams including several specialties and experience in this field are required too. Therefore, this type of procedures should only focus on interventional cardiologists and experienced centers to obtain optimal results.

The future of structural and congenital heart procedures for the management of congenital heart disease is a major first leap that should be interpreted as a snapshot of the state of interventional procedures to treat congenital heart disease, the activity, and results obtained nationwide. This will help standardize procedures and obtain excellent results.

FUNDING

None whatsoever.

CONFLICTS OF INTEREST

None reported.

REFERENCES


