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SCIENTIFIC EDITORIAL

## Transcatheter interventions in congenital heart disease: We must have the means to fulfil our ambitions

*Cathétérisme interventionnel dans les cardiopathies congénitales: nous devons avoir les moyens de nos ambitions*

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As a result of improvements in surgical and interventional cardiac procedures, the majority of children with congenital heart defects can now be expected to reach adulthood. Hence, children and adults with congenital heart disease (CHD) constitute an ever-growing and challenging population, especially those with complex defects. Regarding the available therapeutic armamentarium for these patients, transcatheter interventions have evolved exponentially in recent decades, and are now replacing surgical procedures in a wide variety of defects. This encouraging evolution has been made possible because of the ingenuity and imagination of pioneers who have designed dedicated devices or innovative procedures, despite the limited support of manufacturers. The collaboration between interventionists and their surgical colleagues has also led to the development of hybrid

**Abbreviations:** AEPC, Association for European Paediatric and Congenital Cardiology; CHD, congenital heart disease; ESC, European Society of Cardiology.

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MOTS CLÉS

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interventions, which are likely to allow less invasive therapy of an increasing number of defects in the future. Despite the promising prospects for our discipline in France, great challenges remain to ensure that children and adults with CHD will continue to benefit from safe percutaneous interventions. Those challenges are:

- to define the optimal conditions for delivery of care regarding percutaneous procedures in patients with CHD, and provide expert and evidence-based recommendations for diagnostic and interventional cardiac catheterization;
- to develop reliable national data-collection tools and registries, allowing accurate evaluation of long-term patient outcome after transcatheter interventions;
- to maintain the "French Touch" tradition regarding innovations and development in the field of CHD—addressing in particular the concerns raised by implanting percutaneous devices in growing hearts.

When discussing the optimal conditions for successfully performing interventional pediatric and adult congenital cardiac catheterization, the latter invariably leads to the question of the number of procedures performed (the center's volume) and the presence or not of cardiac surgery capabilities on site or even in the same building, in order to address any procedural complications. While this debate is certainly not new, it remains relevant nonetheless. Recently, the Association for European Paediatric and Congenital Cardiology (AEPC) and the European Society of Cardiology (ESC) published a position paper proposing the organization of care in interventional catheterization for adults with CHD [1]. For the authors, it is clear that not only must cardiac surgery be available on site (with the volume of activity being a decisive factor in the quality and safety of the procedures), it is also imperative for the proper training of future generations of interventionists. Indeed, beyond the parochial turf war, it is this very point that is most central.

In France, the situation is hardly resolved, and we can expect that forthcoming authorizations will finally address these issues. For example, should we require congenital cardiac surgery to be adapted to the age of the patient on site, and should we set minimum thresholds of activity per center to ensure the quality and safety of the patients? Those centers that do not fulfill the conditions that the learned European societies describe as essential for carrying out invasive activities argue that the latter do not take into consideration local needs and equitable territorial distribution. Their arguments are that patient care is still as it always has been, that results are satisfactory, that the use of surgery is relatively rare and that the concept of volume does not take into account operator experience. Moreover, these same centers criticize not taking into account the volume per operator, which is sometimes more substantial in a center where a single operator is responsible for all the activity, whereas in larger centers the activity is often shared between several operators. While these arguments are certainly valid, we must recognize that catheterization activity has changed in recent years, and that we have no national database enabling us to analyze and compare the results. Congenital cardiac catheterization has undergone significant changes in the last 20 years and, as a result, diagnostic catheterization has experienced a sharp decline, being supplanted by echocardiography (transthoracic, transoesophageal, three-dimensional), computed tomography scanning and magnetic resonance imaging. Nowadays, catheterization has become almost exclusively interventional, with various procedures having the particularity of being performed on small groups

of patients. All of these changes indubitably raise the central question of training and maintenance of expertise. Until a few years ago, most operators oversaw pediatric and congenital catheterization along with acquired heart diseases and coronary interventions. The evolution of practices and necessary specialization means that the practice of congenital catheterization today is relatively exclusive, especially when it is performed by career pediatricians, which means that some operators may have reduced activity. While this paradigm shift may not be a limitation for the older interventionists, who were able to advance their training over time as they progressed within the discipline, it is conversely assuredly the case for the younger interventionists, who must acquire an increasingly demanding and increasingly varied technical skillset, especially when the volume of the center does not enable such activity. Very often, experienced operators have a hard time sustaining their activities and finding a multitasking successor who will agree to work in that environment and under those conditions.

With regard to the ESC Working Group recommendations, it is likely that, similar to that reported for patients operated on by surgeons [2,3], transcatheter interventions in the adult CHD population are managed better by operators who are skilled in the care of CHD lesions. Given the importance of both care management and training requirements for safety, a classification of Level 1 and 2 centers performing congenital interventions has been proposed. For both levels, the presence of an on-site congenital cardiothoracic surgeon is mandatory to manage complications swiftly in emergency situations (tamponade, vessel rupture and extracorporeal circulatory support), and with an associated team (anaesthesiologists and intensivists) available 24 hours/day for Level 1. A Level 2 center must perform at least 60 selected subsets of usual interventions, such as atrial septal defect, patent ductus arteriosus closure, pulmonary valve balloon dilatation, etc. A Level 1 center must perform at least 100 cases, and practice the full range of interventions. If the caseload cannot be achieved within that center, then operators should be prepared to work at more than one site in order to maintain quality and fulfill administrative requirements. This last point is probably the most important to maintain a qualified organization status in Level 2 centers. A regional arrangement between Level 2 and Level 1 centers is obviously the only means to ensure qualified education and training, and be attractive to young physicians.

In any system of delivery of care, standardization of practices and data-collection tools are among the most important cornerstones. Although the current trend of our

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specialty is a move towards more tailored management of patients with CHD, practical guidelines from national or international scientific societies provide a useful framework for “real-life” clinical decision making. In the field of congenital and pediatric cardiac catheterization, dedicated guidelines are scarce. Other than the American Heart Association scientific statement, dating back to 2011 [4], no French or European texts are currently available to summarize or guide the practical indications and timing of percutaneous interventions. Therefore, our community must increase its efforts in that direction, by drafting national guideline statements or increasing its involvement in such projects at the European level, through the AEPC Interventional Cardiology Working Group. In addition, a national database of pediatric and congenital transcatheter procedures should be implemented in the near future. Such registries could be useful for patients, parents and physician counseling with regard to the risk factors and outcomes of a specific intervention, as well as for interventionists in order to improve their practice.

One other major challenge that we must face relates to future developments in congenital percutaneous procedures. In the field of CHD, our country has always been a major player in technical innovations, the most recent obviously being the development of the percutaneous pulmonary valve implantation technique in 2000 [5–7]. Nowadays, congenital interventionists are still innovating, in particular by developing procedures inspired by surgical techniques, such as transcatheter Potts anastomosis creation or total cavopulmonary shunt completion [8–10]. Future challenges include the use of bioabsorbable materials for shunt closure devices and tissue engineering technology for percutaneous valves, taking into account the concerns raised by implanting devices in growing hearts. Our community must provide itself with the technical and economic means to enable French researchers to play a key role in these developments. National research grants, research fellowship programs, multi-institutional collaborations and partnerships with manufacturers should be targeted toward this goal.

This special issue of Archives of Cardiovascular Diseases—dedicated to percutaneous interventions in CHD—demonstrates the quality of collaborative work involving French centres, and opens the door to future developments that will allow us to face the remaining challenges of this specialty.

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The author declares that he has no competing interest.

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