Ethics of congenital heart disease interventions: "Can do versus ought to do"dilemma

Survival for children with congenital heart disease (CHD) has significantly improved over the last four decades or so due to advancements made in cardiovascular care. In most high-income countries, 90% of such children survive to adulthood. Conventionally, surgery has been the primary treatment for most CHDs requiring an intervention. Technological advances in the transcatheter treatment have shifted the care of some of the CHDs away from surgical procedures toward less invasive, nonsurgical interventions. Although the first transcatheter intervention, balloon atrial septostomy, was performed by Dr Rashkind in the 1960s,[1] the "real boom" started with the first pulmonary valve balloon dilation in the 1980s.[2] This technique replaced surgical valvotomy as the first-line treatment for pulmonary stenosis at all ages, including neonates. Further advancements in imaging techniques and hardware have expanded the list of lesions that can be treated in the cardiac catheterization lab with excellent outcomes. Since the burden of CHD in India is massive, the number of cardiac interventions is rapidly growing to meet this disease burden. These transcatheter procedures have made an enormous impact on the lives of patients and their families, not only by avoiding sternotomies but also by resulting in prompt recovery. Despite these benefits, new challenges are emerging. The practice of medicine is transforming from a patient-centric to a procedure-centric approach. Just because a transcatheter intervention is available at a low complication rate and a good procedural outcome, should one do it?

It is well established in several studies worldwide that a number of interventional procedures are being overdone, in high-income as well as in resource-poor countries.[3] This type of medical practice is more likely to cause harm than good and consume resources, which are already sparse in low- and middle-income countries. Studies from the USA have shown that 30% of all medical spending is unnecessary and does not add value to patient care.[4,5] In the case of coronary artery disease, significant concerns have been raised about the overuse or inappropriate use of stent procedures. In one second-opinion center in India, 55% of recommended cardiac stents or surgery were deemed inappropriate (unpublished observations).[6] A similar trend is catching up for interventions in CHD, which at times is attributed to the nonavailability of on-site surgical facilities. It is a fact that India has a significant shortage of pediatric cardiac surgeons and surgical centers compared with the number of pediatric cardiologists with access to cardiac catheterization labs. However, ethical medical practice is every patient's right, and careful decision-making is essential.[7]

Medical ethics has four basic principles, namely autonomy, justice, beneficence, and nonmaleficence. The last one, do no harm, is the cornerstone of medical ethics and is incorporated in the Hippocratic Oath. It is the duty of the treating physician to provide objective, scientific information and experience related to a proposed intervention, discussing the risks and benefits, as well as alternative options. Performing unwarranted interventions or procedures where safety data is still evolving or where surgical treatment is considered safer amounts to unethical practice.

Some of the common examples where the principle of nonmaleficence is violated are listed in the Table 1.

Some complications, immediate or long-term, arising from an intervention may be more life-threatening than the disease itself. Examples include the development of aortic obstruction following device closure of patent ductus arteriosus or aortic regurgitation developing following ventricular septal defect device closure. In such cases, one may have to remove the device. At other times, the complication may not be treatable, e.g., development of left ventricular dysfunction long after ventricular septal defect device closure, secondary to unattended conduction disturbance. One will not find many reports of such complications in the scientific literature, apart from a few where success has been achieved in managing them.[8-14] However, many of us have either experienced unsuccessful procedures in our practice or have heard from our colleagues. One more aspect that needs attention is that overuse of interventions can result in cumulative radiation exposure, which is of specific concern in growing children.

The risk–benefit ratio of any procedure can only be correctly ascertained by a prospective multicenter study with standardized follow-up protocols and with an independent group examining follow-up outcomes.[15] Such studies are performed to assess outcomes after surgical valve procedures. In the past, the valvuloplasty and angioplasty of congenital anomalies (VACA) registry enabled unbiased assessment, and this information led to indications for specific procedures, such as balloon pulmonary valvotomy.[16] We do not have such studies for device closures or pulmonary valve implants. Most Indian studies also lack a systematic long-term follow-up.

Table 1: Examples of interventions with little evidence base of symptom or survival benefits

Intervention	Remarks
Small membranous VSD	No evidence of benefit; definite risk of potential harm; Particularly risky in infants
Sub-pulmonic VSD	Potential risk of injury to the aortic valve
Small muscular VSD	No benefit likely if the defect is hemodynamically insignificant
Silent PDA	No proven benefit: Number needed to treat for prevention of a single IE >1000
ASD with insignificant shunt	No proven benefit, especially in older patients
ASD with pulmonary hypertension	Potential risk of harm
Patent Foramen Ovale	RCTs and head-to-head comparisons have not shown a reduction in events
Sinus venosus ASD	Potential need for life-long antiplatelet medications; Long-term safety not established
Stenting of coarctation	Despite the elimination of gradients, there is no proven long-term benefit in reducing CV events
Balloon dilatation of subaortic membrane	Benefit unlikely, especially for thick membranes
Insignificant coronary arteriovenous fistula with normal sized cardiac chambers	These have a benign course and sometimes close spontaneously
Device occlusion of a small hemodynamically insignificant paravalvular leak without hemolysis	No proven benefit

ASD: Atrial septal defect, IE: Infective endocarditis, PDA: Patent ductus arteriosus, RCT: Randomized controlled trial, VSD: Ventricular septal defect, CV: Cardiovascular

Centers with expertise can be identified for new, innovative, or less well-established transcatheter interventions. The outcomes and follow-up data should be made available for these new procedures. Once the success of procedures is established, the expert center can mentor cardiologists from other centers. A classic example is that of fetal cardiac interventions. Once successfully performed in one or two expert centers, training can be imparted to other centers. This strategy, though ideal, may be hard to implement in an unregulated environment.

DRIVERS OF THE CURRENT SITUATION

In India, there is no system of clinical audit, and the entire medical programs are largely unregulated, allowing nonevidence-based management to flourish. No formal training/certification is required for performing cardiac interventions in children after successful training in pediatric cardiology. In most instances, a pediatric cardiologist is the gatekeeper, so there is inherent bias toward nonsurgical interventions. The pros and cons of the procedure and alternate options may not have been discussed in detail with the family.

The fee-for-service model, as it exists in many private health care systems, often encourages cardiologists to perform more interventions that may not be strictly evidence-based to "meet the target." The disproportionate incentive for doing a procedure drives inappropriately indicated interventions. This shifts the focus away from the patient and towards the procedure. Success in the eyes of administrators, peer groups, and industry partners is largely measured by numbers. There are instances of pediatric cardiologists traveling to do elective procedures in catheterization laboratories having suboptimal infrastructure and no surgical backup. Industry plays a very important role in advancing new technologies and innovations, but its influence can extend to research agendas, guideline formulation, and even scientific programs at conferences.

A common justification for an intervention is "if I don't do it, someone else will." At times, a fear-based communication is used to secure immediate consent for an elective procedure ("Time-Bomb" tactic). Some practitioners go an extra mile for tests and interventions to avoid lawsuits (defensive medicine). Sometimes, the family or patient feels that nonsurgical treatment is better because it is less painful and allows for early recovery. Shared decision-making is very important in such instances.

Injudicious interventions can lead to complications, thereby harming the patient. In addition, it represents a significant financial waste for the family and the healthcare system. According to a recent report from the World Health Organization, out-of-pocket health expenditures are impoverishing 55 million Indians annually, with over 17% of households incurring catastrophic levels of health expenditures.[17] In 40% of households, out-of-pocket expenditures for treatment are financed by the sale of properties and the lending of money.[18] Most patients with CHD are not insured (approximately 70%), and such procedures can push their families into extreme poverty and debt.

WAY FORWARD

There is no denying the fact that technology and innovations have transformed the lives of millions of children with CHD. It is time to be circumspect to ensure that patient benefit remains the supreme goal and clinical

science is not forgotten. Several established fundamental steps of clinical practice need to be revisited to achieve this goal.

Shared decision making

Trust is the very essence of the doctor–patient relationship in medical practice. Patients and their families must be actively involved in understanding the risks and benefits of a procedure. In many instances (e.g., closure of sinus venosus atrial septal defect or transcatheter Fontan), the surgical team should also be involved in decision-making. The whole process needs to be transparent, with alternative management options also discussed.

Clinical audits at the national level

A central nationwide clinical audit body is the need of the hour. Some countries have task forces to identify methods to eliminate unnecessary procedures and deliver quality care at low cost. One such example is the National CHD audit, established in 2000, which covers the United Kingdom and the Republic of Ireland.[19] It assesses patient outcomes after therapeutic pediatric and congenital cardiovascular procedures, including surgery and transcatheter interventions. Such audits are meant to improve service delivery and outcomes for children with CHD.

Training the next generation of pediatric cardiologists is one of the most important aspects that will influence how interventional pediatric cardiology is practiced in the future. Ethical practices that prioritize an individualistic approach over procedural volume should be rewarded. The curriculum should incorporate bioethics and self-audit.

Role of professional scientific societies

National-level scientific associations can play a constructive role in ensuring good outcomes. The Cardiological Society of India and the National Intervention Council are encouraging centers to enter data in real-time, web-based registries to audit procedures and improve transparency. Most high-volume centers are part of the registry. The Pediatric Cardiac Society of India should also take the lead in ensuring transparency of transcatheter procedures by instituting web-based multicenter registries. It should come out with guidelines/recommendations for appropriateness criteria of interventions meant to benefit children with CHD.

The patient's well-being and safety should be at the center of all decisions. The "Choosing Wisely" campaign was launched in the USA by the American Board of Internal Medicine Foundation in 2012 and has since been launched in 30+ countries. It is based on five principles, i.e., physician-led, patient-focused, evidence-based, multiprofessional, and transparent. Medical specialty societies compile lists of tests and procedures in their specialties based on strong scientific evidence of overuse, potential harm, or excessive cost. This campaign is already being used for cancer care in India.[20] There are several other similar ways reported in the literature that can be adopted to avoid overuse of transcatheter procedures. It is important to remain patient-centered and not procedure-centered. We, the professionals in the pediatric cardiac care community, need to devise a solution that prevents inappropriate or unnecessary interventions while allowing the freedom to try novel interventions without risking patients' lives.

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