Simulation for Safety in the Pediatric Cardiac Catheterization Laboratory

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Abstract

Treating congenital heart disease is a high-risk, high-benefit scenario, be it in the operating rooms or in cardiac catheterization labs. Inherent to the high-risk nature of the disease, adverse events of varying severity can happen during cath or surgical intervention. These have been traditionally the 'real' clinical teaching for the physician. Simulation technology helps physicians to be trained stress-free in zero-risk environments, especially for the low-frequency, high-risk events. But as always, introduction of new technology faces barriers, so is the case with simulators. Anesthesiology proudly compares itself to the aviation industry, which had also ridiculed aviation simulators in the 1970s. Now they are mandated by all worldwide aviation training authorities. Maybe its time for the anesthesiologists to take the lead in simulation in the health care sector too.

Keywords

- ► pediatric cardiac catheterization laboratory
- ► safety in catheterization laboratory
- ► simulation

Introduction

If we were to trace the origins of use of simulation in medicine, it would probably be the report To Err Is Human: Building a Safer Health System, Institute of Medicine, 1999.[1] This provocative report put the focus squarely on medical errors, a distinctly unpopular topic with physicians and hospitals thus far. Publications regarding clinical safety increased multifold since this report. This led to the birth of a new discipline, the rising star of clinical sciences, Patient Safety. The organizing principle of this official new discipline was that the root cause of any medical error is not bad doctors or any one health care worker; it is bad systems. This concept was transforming, as it aims at taking away the misplaced focus on individual error.

India is still playing catch up to this concept, as the knee-jerk reaction still remains blame and shame of individual doctors, instead of a root cause analysis of the event. There has been a recent spate of such unfortunate events with respectable Delhi hospitals. Indian media's scrutiny of such untoward events or deaths has damaged the reputation of many brilliant well-meaning doctors and has brought about a general sense of public mistrust in the medical system. The medical community must use this as an opportunity for health literacy and awareness of patient safety among the general public.

The underlying principle of simulation in health care is to increase patient safety and improve clinical outcomes by increasing the proficiency of health care workers working individually or in complex team environments. The learning curve is much shorter and steeper, if we can learn without life-threatening consequences to our patients and without mental anguish to us. It is well known that whenever a patient dies, the second victim is always the treating doctor who blames himself, has a deep sense of guilt, and, in extreme cases, has led to physician suicides. The adoption of simulation in our health care system(s) will and should be viewed as being more accountable, more ethical by the public we serve, as well as less stressful for the doctors in training.

Twenty-first century health care relies heavily on interventional radiology suites for cardiology, neurology, and gastroenterology procedures. This review will focus on simulation for interventional pediatric cardiology, pediatric cardiac surgery, and hybrid procedures.

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Due to the complex and heterogeneous nature of congenital heart disease, it is impossible to cover the entire disease spectrum during the fellowship year(s). A thoroughly researched simulation curriculum, even low fidelity, prepared by national faculty in conjunction with international leaders in the field can be a boon in this setting.

Simulation in Pediatric Cardiac Cath Laboratory: Why

The cardiac catheterization laboratory consists of a procedure room and a control room. The procedure room includes a procedure table, fluoroscope, anesthesia machine, contrast injectors, and different catheters. The control station has a glass window to shield from radiation. During our 1-year internship and the 3-year anesthesia residency, limited time is spent in these remote sites such as interventional radiology. Most programs in India have no mandated number of pediatric cases to be done, and most government hospitals have the pediatric patient population mixed with adults. As a result, most anesthesia residents even after completion of their course have minimal to no exposure to the risks involved in the pediatric patient population, pediatric cardiac surgery, or pediatric catheterization laboratories.

There is also the disease heterogeneity problem. Cardiac catheterization in pediatrics and for adults with congenital heart disease encompasses a broad range of procedures, some of which occur infrequently, precluding assessment of risk for individual procedure types. Further, there is variation in the frequency of different procedures between centers and practitioners, and a wide variety of adverse outcomes can occur in different interventions.[2]

In 2007, eight pediatric cardiac centers in the United States started a collaborative project called Congenital Cardiac Catheterization Project on Outcomes (C3PO), in which procedure and patient specific data are collected and compared across these eight centres.[3,4] One of the primary goals of this data was risk stratification according to procedure complexity. This was basically done by analyzing the adverse events that occurred during the procedure, such as cardiac arrest, blood transfusion, surgery, neurological complication, device embolization, etc. This risk stratification was initially judgement and consensus based, and as the data rolled in, it became empirical based (►**Table 1**). This same C3PO group then added patient-specific hemodynamic variables to the procedural complexity to predict adverse events. These four important hemodynamic variables associated with adverse outcomes were: systemic ventricular end-diastolic pressure (EDP) ≥ 18 mm Hg, a systemic saturations < 95% (or < 78% if single ventricle), mixed venous saturation < 60% (or < 50% if single ventricle), and pulmonary artery systolic pressure ≥ 45 mm Hg (or mean ≥ 17 if single ventricle). These easily and commonly measured factors of hemodynamic vulnerability, when combined with the previously validated procedure type risk categories (►**Table 1**) and patient age, were applied to make comparisons of the outcome of high-severity adverse events by adjusting for some of the case mix differences at different centers. This was done by multivariable logistic regression and called Catheterization for Congenital Heart Disease Adjustment for Risk Method (CHARM).[7] This allowed for adjustment of case mix complexity and therefore allowed comparisons of adverse events among institutions performing catheterization for congenital heart disease. There were several groups gathering this type of catheterization data, including C3PO, the Mid-Atlantic Group of Interventional Cardiology (MAGIC), and the Congenital Cardiovascular Interventional Study Consortium (CCISC), with limited ability to cross-communicate between the systems. This led to the birth of the Improving Pediatric and Adult Congenital Treatment (IMPACT) registry in 2011, part of the National Cardiovascular Data Registry (NCDR), which is a United States-based registry collecting information on pediatric and adult patients with congenital heart disease undergoing diagnostic or interventional cardiac catheterization.

With all this quantification of quality measures for the congenital catheterization laboratory, these practitioners started to look at the many sedation-staffing models that existed in the United States. Sedation and anesthesia practices in congenital cardiac laboratories varied from registered nurse supervised by cardiologist to registered nurse supervised by anesthesiologist, general anesthesiologist, and the pediatric cardiac anesthesiologist. After years of pro-con debates regarding the staffing of pediatric cardiac catheterization laboratories, the United States came to a consensus[2] in 2017. This paper, which is an expert consensus statement on the types of sedation and personnel necessary for the procedures performed in the pediatric cardiac catheterization laboratory, emphasizes risk stratification of patients and procedures before catheterization. The assignment of registered nurse or physician anesthesiologist is thus decided, based on the 10-component scoring system, the Catheterization Risk Score in Pediatrics (CRISP) score.[2] This tries to ensure that the assigned sedation provider understands the complex pathophysiology of congenital heart disease and is prepared for the anticipated adverse events associated with the procedure. Odegard et al from Children's Hospital Boston cardiac anesthesia team had published a significant reduction in cardiac arrests in catheterization laboratory after having changed their resource allocation and communication protocol.[5] This study probably was the impetus for the formation of a multi-institutional collaborative leading to the CRISP score development.

Simulation for Technical Skills

Interventional cardiac procedures for congenital heart disease are varied and complex. There is enormous heterogeneity of the disease. There are constantly new technical advances. Simulation is particularly useful in this patient and disease subset, for the fellows-in-training, as well as the experienced practitioner to keep up with the latest technical innovations. Training programs in the United States mandate that cardiovascular and interventional cardiology fellowship training programs have simulation as a part of training.[6]

Cardiac and vascular surgery fellowships are now including endovascular procedures in their training for involvement

Table 1 Procedure type risk categories

	Risk category 1	Risk category 2	Risk category 3	Risk category 4
Diagnostic case	Age ≥ 1 year	Age ≥ 1 month < 1 year	Age < 1 month	
Valvuloplasty		Pulmonary valve ≥1 month	Aortic valve ≥ 1 month pulmonary valve < 1month Tricuspid valve	Mitral valve Aortic valve <1 month
Device or coil closure	Venous Collateral	PDA	Systemic surgical shunt	VSD
	LSVC	ASD\PFO	Baffle leak	Perivalvular leak
		Fontan fenestration	Coronary fistula	
		Systemic to pulmonary artery collaterals		
Balloon angioplasty		RVOT	Pulmonary artery < 4 vessels	Pulmonary artery ≥ 4 vessels
		Aorta dilation < 8 atm	Pulmonary artery ≥ 4 vessels all < 8 atm	Pulmonary vein
			Aorta > 8 atm or CB	
			Systemic artery (not aorta)	
			Systemic surgical shunt	
			Systemic to pulmonary collaterals	
			Systemic vein	
Stent placement		Systemic vein	RVOT	Ventricular septum
			Aorta	Pulmonary artery
			Systemic artery (not aorta)	Pulmonary vein
				Systemic surgical shunt
				Systemic pulmonary collateral
Stent redilation		RVOT	Pulmonary artery	Ventricular septum
		Atrial septum	Pulmonary vein	
		Aorta		
		Systemic artery (not aorta)		
		Systemic vein		
Other	Myocardial biopsy	Snare foreign body	Atrial septostomy	Atrial septum dilation and stent
		Trans–septal puncture	Recanalization of jailed vessel in stent	Any catheterization < 4 days after surgery
			Recanalization of occluded vessel	Atretic valve perforation

Abbreviations: ASD, atrial septal defect; CB, cutting balloon; LSVC, left superior vena cava; PDA, patent ductus arteriosus; PFO, patent foramen ovale; RVOT, right ventricular outflow tract (RVOT includes right ventricle to pulmonary artery conduit or status post–RVOT surgery with no conduit); VSD, ventricular septal defect.

in hybrid procedures, such as stage I surgery for the hypoplastic left heart syndrome.

The anesthesiologists and intensivists should try to keep pace with this as they form an essential component of this high-stress, high-stakes care team. The dynamic nature of catheterization laboratory, with catheters blocking or opening vessels and holes transiently or permanently, new hemodynamic information comes at us at a very fast pace. Clinicians providing anesthesia services for patients with congenital or acquired heart disease in the catheterization laboratory must be prepared to appropriately manage not only the airway with the cardiopulmonary interactions, but must also understand that airway obstruction and/or hypoventilation affects the patient's unique physiology and could have catastrophic effects in patients with structural heart disease. Clinicians must balance providing adequate sedation/anesthesia to the patient with the ability to anticipate, rapidly identify, and appropriately respond to hemodynamic changes and deterioration that might require cardiopulmonary resuscitation, initiation of systemic vasoconstrictors, pulmonary vasodilators, treatment of massive pulmonary hemorrhage, and emergent cannulation for extracorporeal membrane oxygenation (ECMO) support. The invisible radiation hazards, the heavy lead aprons while working, the biplane cameras moving around the patient head, the workplace ergonomics, and dim lighting makes for poor workplace ergonomics and the catheterization laboratory environment even more challenging. The anesthesiologist must be comfortable following all the wires and catheters fluoroscopically, to simultaneously get all the information the cardiologist is getting for the patient concerned, and tailor his fluids, anesthetics, inotropes accordingly. Knowledge of the pathophysiology is critical for these fast moving cases, as the cardiologist does not always communicate all potentially low cardiac output maneuvers he is about to perform. CPR drugs in appropriate dilutions should always be kept ready for potentially high-risk interventions.

Simulation for Nontechnical Skills

On January 15, 2009, US Airways Flight 1549 hit geese shortly after takeoff from LaGuardia Airport in New York City. Both engines lost power, and the crew quickly decided that the best action was an emergency landing in the Hudson River. Due to the crew's excellent performance, all 155 people aboard the flight survived. The health care industry is still struggling to establish this culture of open communication and collaboration in a non-threatening way. Effective communication has to be conceptualized and taught as an essential clinical skill.

Communication failures are more likely to occur in health care than in aviation cockpit settings for a variety of reasons, including the wide range of patients, staff, distractions, and interruptions that are prevalent in most clinical interactions. Although there are usually clear differences in knowledge, skills, and experience between a pilot and co-pilot, safety in aviation is encouraged to take priority over deference, with simple measures such as the use of first names in interactions. This is not common practice in health care, since it is inherently hierarchical, with resultant barriers to assertiveness. Dr Atul Gawande[7] conducted confidential interviews with randomly selected surgeons from three Massachusetts teaching hospitals to elicit detailed reports on surgical adverse events resulting from errors in management ("incidents"). The most commonly cited system factors contributing to errors were inexperience/lack of competence in a surgical task (53% of incidents), communication breakdowns among personnel (43%), and fatigue or excessive workload (33%).

In aviation, more than 50 years of research has taught that superior cognitive and technical skills are not enough to ensure safety: effective teamwork skill is a must. Similar observations are now being made in perioperative medicine. David Gaba and his team at Stanford have realized the potential of training entire teams, and not individuals, and adopted the aviation crew resource management into anesthesia crisis resource management.[8]

"First do no harm," said Hippocrates. In the twenty-first century, simulation is the safest way to try and ensure this for our most fragile patient population.

Conflict of Interest
None.

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