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Original Article

Characteristics and safety of interventions and procedures performed during catheterisation of patients with congenital heart disease: early report from the national cardiovascular data registry

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Abstract *Objectives:* The objective of this study was to report procedural characteristics and adverse events on the data collected in the IMproving Paediatric and Adult Congenital Treatment registry. *Background:* The IMproving Paediatric and Adult Congenital Treatment– registry is a catheterisation registry focussed on paediatric and adult patients with congenital heart disease who are undergoing diagnostic catheterisations and catheter-based interventions. This study reports procedural characteristics and adverse events of patients who have undergone selected catheterisation procedures from January, 2011 to June, 2013. *Methods:* Demographic, clinical, procedural, and institutional data elements were collected at participating centres and entered via either a web-based platform or software provided by the American College of Cardiology-certified vendors, and were collected in a secure, centralised database. For the purpose of this study, procedures that were not classified as one of the 'core' IMproving Paediatric and Adult Congenital Treatment procedures originally chosen for additional data collection were identified and selected for further data analysis. *Results:* During the time frame of data collection, a total of 8021 cases were classified as other procedures and/or multiple procedures. The most commonly performed case types – isolated or in combination with other procedures – were right ventricular biopsy in 3433 (42.8%), conduit/MPA interventions in 979 (12.3%), and systemic pulmonary artery collateral occlusion in 601 (7.5%). For the whole cohort, adverse events of any severity occurred in 957 (12.0%) cases, whereas major adverse events occurred in 113 (1.4%) cases; six patients (0.1%) died in the catheterisation laboratory. *Conclusions:* The IMproving Paediatric and Adult Congenital Treatment registry has provided important data on the frequency and spectrum of cardiac catheterisation procedures performed in the present era. For many procedures, more data and work are needed to identify more subtle differences between case categories, especially as it relates to the incidence of major adverse events, and to further develop a risk-adjustment methodology to allow equitable comparisons among institutions.

Keywords: Cardiac catheterisation; adverse events; congenital heart disease

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Background

A variety of registries such as Congenital Cardiac Catheterization Project on Outcomes, Mid Atlantic Group of Interventional Cardiology, and Congenital Cardiovascular Interventional Study Consortium have reported data on outcomes of congenital cardiac catheterisation.[1–4] The data were frequently provided for isolated procedures such as patent ductus arteriosus, pulmonary valvuloplasty, pulmonary artery rehabilitation, atrial septal defect closure, as well as for the treatment of coarctation.[5–8] Other reports focussed on a general description of the frequency of adverse events as well as risk-adjustment methods.[9] Limitations of the currently existing registries include the total number of cases submitted as well as the number of participating centres.

The IMproving Paediatric and Adult Congenital Treatment registry is now operating in over 90 hospitals and has recently reported results on selected "core" procedural categories, which were originally chosen to collect additional procedural details for future assessment of procedure-specific risk and efficacy outcomes.[10] This original selection of "core" procedures included mainly procedure types that were considered "common" and potentially amenable for the development of additional procedural outcome metrics. The publications on those "core" procedures did not include data on cases that were not captured within these "core" IMproving Paediatric and Adult Congenital Treatment procedural categories; however, these "non-core" cases account for a large number of the procedures that are performed in the catheterisation laboratory, and although many of these cases have no clearly established outcome parameters, providing basic data on these procedures could aid in this process. The purpose of this report was to describe the frequency and basic procedural characteristics of those "non-core" cases, as well as providing data on associated adverse events.

Methods

General methodology

The IMproving Paediatric and Adult Congenital Treatment registry is an initiative of the American College of Cardiology Foundation with partnering support from The Society for Cardiovascular Angiography and Interventions and the American Academy of Pediatrics, and it has been previously described by Martin et al.[11] The registry collects data for use in the development of performance and quality metrics, quality improvement programmes, and peer-reviewed outcomes research focussed on paediatric and adult patients with congenital heart disease who are undergoing diagnostic catheterisations and catheter-based interventions. Demographic, clinical, procedural, and institutional data elements are collected at participating centres and entered via either a web-based platform or a software provided by ACC-certified vendors and are collected in a secure, centralised database. IMproving Paediatric and Adult Congenital Treatment registry has in place a data quality programme consistent with that described for The National Cardiovascular Data Registry.[12] A comprehensive description of IMproving Paediatric and Adult Congenital Treatment Registry data elements and definitions is available at http://www.ncdr.com.

Specific methodology

The focus of this study was to analyse IMproving Paediatric and Adult Congenital Treatment registry data pertaining to procedural results and outcomes in patients who undergo combined procedures or procedures that were not classified as one of the following IMproving Paediatric and Adult Congenital Treatment 'core' procedures originally chosen for additional data collection: atrial septal defect, device closure of patent ductus arteriosus, pulmonary valvuloplasty, aortic valvuloplasty, coarctation of the aorta angioplasty and stenting, proximal pulmonary artery stenting, and any purely diagnostic cardiac catheterisation. These isolated procedure types had been originally chosen as separate procedural categories within the IMproving Paediatric and Adult Congenital Treatment registry and results on these were previously reported by Moore et al.[10] For the purpose of this study, the above procedure types are referred to as "core" procedures. In contrast, the subjects of this study, which are all other procedures, captured within the IMproving Paediatric and Adult Congenital Treatment registry are referred to as "non-core" procedures.

Registry data from January, 2011 to June, 2013 were collected from a total of 8021 cardiac catheterisation cases. A single trip to the catheterisation laboratory was defined as a case, whereas the term "episode of care" refers to hospital admission following cardiac catheterisation, up to a maximum of 30 days after the procedure or hospital discharge, whichever occurs earlier.

Basic demographic and clinical data were provided for all the cases in this study. The entire study cohort was then separated into various case types, based on the frequency of cases performed, as well as common case characteristics. Table 1 summarises all the cases collected in this cohort, as well as the number of cases of "core" procedures performed within the same time period. Individual data of "non-core" cases were then separated into groups that had no overlap between

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Table 1. Frequency of procedural categories collected within the IMPACT registry.

Procedure	Count (n)
Proximal PA intervention	738 (3.7%)
Balloon angioplasty only	238 (1.2%)
Stent only**	320 (1.6%)
Balloon angioplasty and stent	48 (0.2%)
Balloon and/or stent with other intervention(s)	452 (2.3%)
Peripheral PA intervention	451 (2.3%)
Balloon angioplasty only	160 (0.8%)
Stent only	32 (0.2%)
Balloon angioplasty and stent	20 (0.1%)
Balloon and/or stent with other intervention(s)	239 (1.2%)
Conduit/MPA intervention	979 (5.0%)
Balloon angioplasty only	399 (2.0%)
Stent only	78 (0.4%)
Balloon angioplasty and stent	40 (0.2%)
Balloon and/or stent with other intervention(s)	462 (2.2%)
Multi-level PA intervention (balloon and/or stent in at least two PA locations: proximal, peripheral, conduit/MPA)	331 (1.7%)
Balloon angioplasty and/or stent	267 (1.4%)
Balloon and/or stent with other intervention(s)	64 (0.3%)
Caval vein intervention	236 (1.2%)
Balloon angioplasty only	72 (0.4%)
Stent only	41 (0.2%)
Balloon angioplasty and stent	19 (0.1%)
Balloon and/or stent with other intervention(s)	104 (0.5%)
Pulmonary vein intervention	202 (1.0%)
Balloon angioplasty only	102 (0.5%)
Stent only	17 (0.1%)
Balloon angioplasty and stent	21 (0.1%)
Balloon angioplasty and/or stent + ASD intervention	22 (0.1%)
Balloon and/or stent with other intervention(s)	40 (0.2%)
Aorta	800 (4.0%)
Balloon angioplasty or stent**	671 (3.4%)
Balloon angioplasty or stent with other intervention(s)	129 (0.7%)
Other artery intervention	87 (0.4%)
Balloon angioplasty and/or stent	49 (0.2%)
Balloon and/or stent with other intervention(s)	38 (0.2%)
Other vein intervention	100 (0.5%)
Balloon angioplasty and/or stent	30 (0.2%)
Balloon and/or stent with other intervention(s)	70 (0.4%)
Sano (conduit) or shunt intervention	141 (0.7%)
Balloon angioplasty and/or stent	89 (0.5%)
Balloon and/or stent with other intervention(s)	52 (0.3%)
PDA intervention	105 (0.5%)
Balloon angioplasty and/or stent	90 (0.5%)
Balloon and/or stent with other intervention(s)	15 (0.1%)
Fontan or atrial baffle intervention	50 (0.3%)
Balloon angioplasty and/or stent	27 (0.1%)
Balloon and/or stent with other intervention(s)	23 (0.1%)
Fontan fenestration intervention	36 (0.2%)
Balloon angioplasty and/or stent	18 (0.1%)
Balloon and/or stent with other intervention(s)	18 (0.1%)
ASD occlusion	1434 (7.3%)
Isolated**	1362 (6.9%)
With other intervention(s)	72 (0.4%)
PFO occlusion	203 (1.0%)
Isolated	171 (0.9%)
With other intervention	32 (0.2%)
Fenestration or baffle leak occlusion	160 (0.8%)
Isolated	95 (0.5%)
With other intervention	65 (0.3%)
PDA occlusion	1426 (7.2%)
Isolated**	1375 (7.0%)
With other intervention(s)	51 (0.3%)

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Table 1. *Continued*

Procedure	Count (n)
VSD occlusion	65 (0.3%)
Isolated	44 (0.2%)
With other intervention	21 (0.1%)
Systemic vein to PV collateral occlusion	253 (1.3%)
Isolated	133 (0.7%)
With other intervention	120 (0.6%)
Systemic artery to PA collateral occlusion	601 (3.0%)
Isolated	383 (1.9%)
With other intervention	218 (1.1%)
Other vascular structure device or coil placement	283 (1.4%)
Isolated	184 (0.9%)
With other intervention	99 (0.5%)
Aortic valvuloplasty	357 (1.8%)
Isolated**	340 (1.7%)
With other intervention(s)	17 (0.1%)
Pulmonary valvuloplasty	768 (3.9%)
Isolated**	661 (3.3%)
With other intervention(s)	107 (0.5%)
Mitral valvuloplasty	30 (0.2%)
Isolated	13 (0.1%)
With atrial septal intervention	11 (0.1%)
With other intervention	6 (<0.05%)
Tricuspid valvuloplasty	12 (0.1%)
Isolated	5 (<0.05%)
With other intervention	7 (<0.05%)
Transcatheter pulmonary valve implantation	374 (1.9%)
Isolated	158 (0.8%)
With balloon and/or stent of MPA/conduit	95 (0.5%)
With other intervention	121 (0.6%)
Balloon atrial septostomy	274 (1.4%)
Isolated	241 (1.2%)
With other intervention	33 (0.2%)
Atrial septal intervention (non-BAS)	221 (1.1%)
Isolated	111 (0.6%)
With other intervention	110 (0.6%)
RV biopsy	3433 (17.4%)
Isolated	3372 (17.1%)
With other intervention	61 (0.3%)
Vascular/valvar perforation	35 (0.2%)
Isolated	12 (0.1%)
With other intervention	23 (0.1%)
Diagnostic only catheterisation**	7010 (35.5%)

ASD = atrial septal defect; BAS = balloon atrial septostomy; IMPACT = IMproving Paediatric and Adult Congenital Treatment; MPA = main pulmonary artery; PA = pulmonary artery; PDA = patent ductus arteriosus; PFO = patent foramen ovale; RV = right ventricle; VSD = ventricular septal defect

Case types marked with ** were "core" IMPACT case types and are not further analysed in detail within this report. This includes isolated cases of the following categories: diagnostic catheterisation, balloon pulmonary valvuloplasty, balloon aortic valvuloplasty, PDA occlusion, ASD occlusion, balloon angioplasty or stenting of coarctation, and proximal PA stenting. Percentages refer to the total number of cases in the registry (n = 19,760 = 100%) and a case can be listed in more than one procedural category

individual case types (Table 2). Data collected for these individual case types included weight, case time, contrast administered, as well as data on adverse events and death (Fig 1).

Adverse events captured within the IMproving Paediatric and Adult Congenital Treatment registry are listed in Table 3. Major adverse events are defined as the need for permanent or temporary pacemaker, cardiac arrest, cardiac tamponade requiring pericardial drainage, embolic stroke, as well as unplanned cardiac surgery due to a catheter-related adverse event. Bleeding events after catheterisation are captured if they are associated with either a drop in haemoglobin of $\geqslant$3 mg/dl, or a transfusion of whole blood or packed red

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Table 2. Case categories without overlap.

Proximal PA	
Balloon	238 (3.0%)
Balloon and stent	48 (0.6%)
Peripheral PA	
Balloon	160 (2.0%)
Stent	32 (0.4%)
Balloon and stent	20 (0.2%)
Conduit/MPA	
Balloon	399 (5.0%)
Stent	78 (1.0%)
Balloon and Stent	40 (0.5%)
Multi-level PA – balloon and/or stent	267 (3.3%)
Caval vein	
Balloon	72 (0.9%)
Stent	41 (0.5%)
Balloon and stent	19 (0.2%)
Pulmonary vein	
Balloon	102 (1.3%)
Stent	17 (0.2%)
Balloon and stent	21 (0.3%)
Other artery and/or vein – balloon and/or stent	79 (1%)
Sano (conduit), shunt, and/or PDA – balloon and/or stent	179 (2.2%)
Fontan and/or baffle – balloon and/or stent	27 (0.3%)
Fontan fenestration – balloon and/or stent	18 (0.2%)
PFO occlusion	171 (2.1%)
Fenestration and/or baffle leak occlusion	95 (1.2%)
VSD occlusion	44 (0.5%)
Systemic vein to PV and/or systemic artery to PA collateral occlusion	546 (6.8%)
Other vascular structure device or coil placement	184 (2.3%)
Mitral and/or tricuspid valvuloplasty	18 (0.2%)
Transcatheter pulmonary valve	
Isolated	158 (2%)
With balloon and/or stent of MPA/conduit	138 (1.7%)
Balloon atrial septostomy	241 (3%)
Atrial septal intervention (±BAS)	129 (1.6%)
RV biopsy	3372 (42.0%)
Vascular/valvar perforation	12 (0.1%)
Other isolated or combined procedures	1056 (13.2%)

BAS = balloon atrial septostomy; MPA = main pulmonary artery; PA = pulmonary artery; PDA = patent ductus arteriosus; PFO = patent foramen ovale; PV = pulmonary vein; RV = right ventricle; VSD = ventricular septal defect
Any case is only listed in one of the case categories. Percentages refer to the total number of 'other' or 'combined' procedures (n = 8021 = 100%)

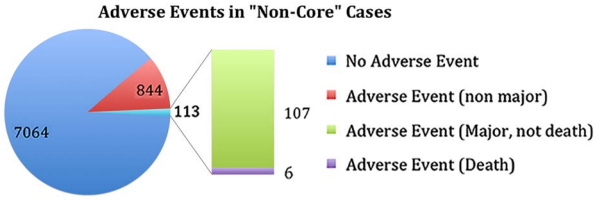

Figure 1.
Adverse events encountered in "non-core" cases.

blood cells, or any procedural intervention/surgery at the bleeding site to reverse/stop or correct the bleeding. Adverse events were reported if they occured at any time from cardiac catheterisation until 30 days after the procedure or hospital discharge, whichever occured earlier (episode of care), except for an embolic stroke, which was reported up to 72 hours after the procedure. If more than one catheterisation procedure was performed during the same episode of care, adverse events were captured until the subsequent cardiac catheterisation, except for bleeding and transfusion events, which are captured only up to 72 hours after the procedure. Death was not included as part of the adverse events, but reported separately as either death in the catheterisation laboratory or death within the same episode of care as defined above.

Inclusion and exclusion criteria

Inclusion criteria:

– Any case submitted to the IMproving Paediatric and Adult Congenital Treatment registry

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Table 3. Adverse events captured within the IMPACT registry.

Any adverse event	Major adverse event
Cardiac arrest	Need for permanent or temporary pacemaker
Air embolus	Cardiac arrest
Arrhythmia	Cardiac tamponade (requiring pericardial drainage)
Arrhythmia requiring cardioversion	Embolic stroke (within 72 hours)
Antiarrhythmic medication	Unplanned cardiac surgery (due to catheterisation AE)
Permanent or temporary pacemaker	
New heart valve regurgitation	
Tamponade	
Embolic stroke	
New requirement for dialysis	
Airway event requiring intubation	
Event requiring ECMO or LVAD*	
Bleeding event	
Bleeding event at the access site	
Haematoma at access site	
Retroperitoneal	
Gastrointestinal or genital-urinary bleeding	
Red blood cell/whole blood transfusion	
Device malposition	
Device thrombus	
Device embolisation	
Unplanned surgery (due to catheterisation AE)	
Subsequent cardiac catheterisation (due to catheterisation AE)	

AE = adverse events; ECMO = extracorporeal membrane oxygenation; IMPACT = IMproving Paediatric and Adult Congenital Treatment; LVAD = left ventricular assist device
*Events requiring ECMO or LVAD will be classified as a "Major adverse event" in the next version of the IMPACT registry (version 2)

Exclusion criteria:

- Any case that only included one of the "core" interventional procedures, as defined in the specific methodlogy section
- Any procedure that was solely diagnostic

Statistics

Basic descriptive data were calculated for all cardiac catheterisation cases and case types meeting the inclusion and exclusion criteria. Continuous variables are presented as median and interquartile range. Categorical variables are presented as frequency, using the number of cases for which the data element was provided as 100%.

Results

Basic demographic and clinical data

Within the IMproving Paediatric and Adult Congenital Treatment registry, a total of 8021 cases were classified as other procedures and/or multiple procedures, performed during 7691 episodes of care. These "non-core" cases formed the study cohort. The median weight was 23.1 kg (interquartile range 10, 9, 53.8). The age was <30 days for 451 (5.6%), equal to 30 days and below or equal to 1 year for 1017 (12.7%), above 1 year and below or equal to 18 years for 5210 (65.0%), and above 18 years for 1343 (16.7%) of the cases. A history of previous cardiac catheterisation was present in 6507 (82.4%) cases, and 619 (9.5%) cases underwent cardiac catheterisation within the preceding 30 days. A history of previous cardiac surgery was present in 6220 (78%) cases, and 996 (16%) cases had cardiac surgery within the preceding 30 days. Single ventricle anatomy was present in 1655 (20.7%) cases.

The majority of cases were performed electively (6738, 84.3%), followed by urgent (962, 12.0%), emergent (259, 3.2%), and salvage (32, 0.4%) procedures. General anaesthesia was used in 6202 (77.5%) cases, with elective intubation at the start in 4935 (61.5%) cases. The median case time was 80 minutes (interquartile range 39, 138), and the median amount of contrast administered was 2.1 ml/kg (interquartile range 0.3, 4.5). A systemic ventricular end-diastolic pressure equal to or above 18 mmHg was present in 352 (8.2%), and a cardiac index equal to or below 2.8 was present in 1663 (25.8%) of the cases.

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Individual procedural data

A summary of all cases performed is listed in Tables 1 and 2. The most commonly performed case – in isolation or in combination with other procedures – was right ventricular biopsy, accounting for 3433 (42.8%) of all "non-core" cases within the IMproving Paediatric and Adult Congenital Treatment registry. Pulmonary artery interventions – in isolation or in combination with other procedures – were performed proximally in 738 (9.2%), peripherally in 451 (5.6%), and at the conduit/main pulmonary artery in 979 (12.2%) cases. Transcatheter pulmonary valve implantation was carried out in 374 (4.7%) cases. Aortopulmonary collaterals were occluded in 601 (7.5%), and venous collaterals were occluded in 253 (3.2%) of the cases.

Isolated case types are listed in Table 4. The longest median case times were seen for combined balloon angioplasty and stent placement in the peripheral pulmonary arteries (178 minutes) as well as the pulmonary veins (180 minutes), whereas the shortest median case times were seen for right ventricular biopsy (38 minutes) and patent foramen ovale occlusion (60 minutes). The only other isolated case type with a case time of <100 minutes was balloon angioplasty and/or stent placement within a Sano conduit, Blalock–Taussig shunt, or patent arterial duct (94 minutes).

Among all, four case types had an associated median use of contrast exceeding 5 ml/kg. These included multi-level pulmonary artery rehabilitation with balloon angioplasty and/or stent placement (5.0 ml/kg), balloon angioplasty and stent placement in the peripheral pulmonary arteries (5.7 ml/kg) or at the right ventricle-to-pulmonary artery conduit/main pulmonary artery (5.8 ml/kg), as well as vascular/valvar perforation cases (5.9 ml/kg).

Adverse events

Data on adverse events for individual case types are listed in Table 4. For the entire cohort, adverse events of any severity occurred in 957 (12.0%) cases, whereas major adverse events occurred in 113 (1.4%) cases (Fig 1); six patients (0.1%) died in the catheterisation laboratory, and 187 patients died within the same episode of care of causes not necessarily related to cardiac catheterisation. Cardiac arrest occurred in 76 (1.0%), cardiac tamponade in 15 (0.2%), embolic stroke in 5 (0.1%), device malposition requiring surgery in 10 (0.1%), device embolisation requiring retrieval in 30 (0.4%), new requirement for dialysis in 11 (0.1%), need for extra-corporal membrane oxygenation in 28 (0.4%), and an airway event requiring intubation in 59 (0.7%) cases. Bleeding events occurred in 140 (1.8%) cases, with 69 (49.6%) cases bleeding at the access site and 44 (31.7%) with a haematoma at the access site. Blood transfusion was administered in 387 (4.8%) cases. Arrhythmias occurred in 186 (2.3%), requiring cardioversion in 55 (29.6%), antiarrhythmic medication in 87 (46.8%), and temporary pacing in 16 (8.6%) of the cases, no permanent pacemaker was required. Secondary to a catheterisation complication, unplanned cardiac surgery was required in 25 (0.3%) and unplanned vascular surgery in 11 (0.1%) cases. Unplanned other surgery was required in 30 (0.4%) cases, 10.0% of which were secondary to catheter-related complications. Red blood cell transfusion was required in 387 (4.8%) cases.

For individual cases, the number of major adverse events was generally very low, and therefore difficult to compare, with only five case categories having more than three cases with a major adverse event. These were balloon angioplasty and/or stent placement in the Sano conduit, shunt, or patent arterial duct (n = 5, 2.8%), balloon atrial septostomy (n = 13, 5.5%), as well as other atrial septal interventions with or without balloon atrial septostomy (n = 10, 7.8%).

There were four case types where the incidence of cases with any adverse event was >30%, which included balloon angioplasty and stent placement in the peripheral pulmonary arteries (9/20, 45.0%), balloon angioplasty and stent placement in the pulmonary veins (7/21, 33.3%), balloon angioplasty and/or stent placement in the Sano conduit, shunt, or patent arterial duct (66/179, 37.5%), as well as vascular/valvar perforation (5/12, 41.7%).

In total, five case categories had <10% of cases with any type of adverse events. These included balloon angioplasty of the caval vein (6/72, 8.3%), patent foramen ovale occlusion (3/171, 1.8%), occlusion of a fenestration or baffle leak (6/95, 6.3%), right ventricular biopsy (108/3372, 3.2%), as well as mitral or tricuspid valvuloplasty (1/18, 5.6%).

Discussion

This report provides an overview of the types of "non-core" cases submitted to the IMproving Paediatric and Adult Congenital Treatment registry, excluding the "core" IMproving Paediatric and Adult Congenital Treatment procedure types that are reported separately.[10] Although a variety of registries have published data on individual case types as well as adverse events, beyond the results of the Congenital Cardiac Catheterization Project on Outcomes registry there are limited multi-centre data available on the frequency of the various case types that are performed in the cardiac catheterisation laboratory in the present era.

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Table 4. Basic characteristics of individual case types within the IMPACT registry.

	Proximal PA		**Multi-level PA**	
	Balloon	**Balloon and stent**	**Balloon and/or stent**	
Number of cases	238	48	267	
Weight	12.7 [8.2, 23.1]	15.9 [9.8, 34.0]	16.6 [10.0, 29.8]	
Procedure time	111.0 [82.0, 146.0]	149.0 [98.5, 178.5]	148.5 [117.0, 212.0]	
Contrast	3.9 [2.5, 5.4]	3.7 [3.0, 5.9]	5.0 [3.5, 6.6]	
Any adverse event	31 (13.0%)	5 (10.4%)	53 (20.1%)	
Major adverse event	2 (0.8%)	0 (0.0%)	3 (1.1%)	
Death in the catheterisation lab	2 (0.8%)	0 (0.0%)	0 (0.0%)	
	Peripheral PA			
	Balloon	Stent	Balloon and stent	
Number of cases	160	32	20	
Weight	13.6 [9.0, 27.6]	13.7 [9.2, 24.7]	13.0 [10.4, 25.4]	
Procedure time	137.0 [100.0, 194.0]	147.0 [101.5, 192.0]	178.0 [145.0, 267.0]	
Contrast	4.3 [0.0, 11.5]	4.9 [3.3, 6.0]	5.7 [3.3, 7.4]	
Any adverse event	22 (13.8%)	7 (21.9%)	9 (45.0%)	
Major adverse event	0 (0.0%)	2 (6.3%)	0 (0.0%)	
Death in the catheterisation lab	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Conduit/MPA			
	Balloon	Stent	Balloon and stent	
Number of cases	399	78	40	
Weight	16.7 [8.5, 43.1]	14.7 [7.6, 34.1]	13.8 [8.3, 26.9]	
Procedure time	117.0 [89.0, 151.5]	123.0 [92.0, 154.0]	159.0 [115.0, 208.0]	
Contrast	3.9 [2.6, 5.4]	4.5 [3.4, 6.2]	5.8 [4.4, 8.3]	
Any adverse event	49 (12.3%)	13 (16.7%)	11 (28.2%)	
Major adverse event	3 (0.8%)	3 (3.8%)	1 (2.6%)	
Death in the catheterisation lab	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Caval vein			
	Balloon	Stent	Balloon and stent	
Number of cases	72	41	19	
Weight	16.9 [10.9, 56.4]	21.5 [10.3, 70.5]	24.3 [12.2, 62.6]	
Procedure time	116.0 [75.0, 148.0]	127.0 [115.0, 175.0]	131.0 [97.0, 230.0]	
Contrast	3.2 [1.8, 4.3]	2.9 [1.8, 3.8]	2.8 [1.7, 4.4]	
Any adverse event	6 (8.3%)	8 (19.5%)	4 (21.1%)	
Major adverse event	1 (1.4%)	1 (2.4%)	0 (0.0%)	
Death in the catheterisation lab	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Pulmonary vein			
	Balloon	Stent	Balloon and stent	
Number of cases	102	17	21	
Weight	9.5 [6.4, 13.9]	11.7 [4.2, 59.9]	9.8 [5.8, 16.4]	
Procedure time	140.0 [105.0, 180.0]	119.0 [104.0, 211.0]	180.0 [118.0, 290.0]	
Contrast	3.1 [2.1, 4.7]	2.8 [1.4, 4.1]	4.5 [3.0, 5.9]	
Any adverse event	25 (25.3%)	5 (29.4%)	7 (33.3%)	
Major adverse event	3 (3.0%)	1 (5.9%)	1 (4.8%)	
Death in the catheterisation lab	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Balloon and/or stent			
	Other artery/vein	Sano/shunt/PDA	Fontan/baffle	Fontan fenestration
Number of cases	79	179	27	18
Weight	20.0 [4.7, 52.5]	3.5 [3.0, 4.9]	55.7 [20.5, 71.0]	18.1 [14.7, 40.5]
Procedure time	118.0 [72.0, 174.0]	94.0 [53.0, 144.0]	129.0 [95.0, 175.0]	139.0 [98.0, 198.0]
Contrast	3.3 [1.9, 5.0]	4.9 [3.3, 7.0]	2.4 [1.5, 3.5]	3.5 [2.6, 4.8]
Any AE	22 (27.8%)	66 (37.5%)	4 (14.8%)	3 (17.6%)
Major AE	1 (1.3%)	5 (2.8%)	0 (0.0%)	0 (0.0%)
Death in the catheterisation lab	1 (1.3%)	1 (0.6%)	0 (0.0%)	0 (0.0%)

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Table 4. *Continued*

	Occlusion			
	PFO	Fenestration/baffle leak	VSD	Collateral (vein/artery)
Number of cases	171	95	44	546
Weight	79.0 [62.5, 92.0]	19.6 [15.5, 34.4]	12.9 [7.2, 24.2]	13.7 [10.2, 25.6]
Procedure time	60.0 [45.0, 78.0]	102.0 [75.0, 128.0]	140.0 [112.5, 176.0]	126.5 [94.0, 173.0]
Contrast	0.1 [0.0, 0.7]	3.9 [2.2, 5.2]	3.8 [2.6, 5.3]	4.3 [3.0, 5.8]
Any AE	3 (1.8%)	6 (6.3%)	12 (27.3%)	78 (14.4%)
Major AE	0 (0.0%)	0 (0.0%)	1 (2.3%)	6 (1.1%)
Death in the catheterisation lab	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

	Transcatheter pulmonary valve	
	Isolated	With balloon/stent of MPA/conduit
Number of cases	158	138
Weight	61.5 [50.3, 79.4]	62.5 [44.0, 73.5]
Procedure time	168.0 [127.0, 212.0]	165.0 [125.0, 217.0]
Contrast	3.1 [2.0, 4.1]	3.4 [2.4, 5.2]
Any adverse event	20 (12.7%)	32 (23.2%)
Major adverse event	3 (1.9%)	3 (2.2%)
Death in the catheterisation lab	0 (0.0%)	0 (0.0%)

	Atrial septal intervention*	
	BAS	Other (±BAS)
Number of cases	241	129
Weight	3.4 [2.9, 3.8]	5.5 [3.5, 13.8]
Procedure time	47.0 [27.0, 88.0]	96.0 [68.0, 145.0]
Contrast	1.6 [0.0, 3.7]	2.8 [1.0, 4.9]
Any adverse event	59 (24.8%)	38 (29.7%)
Major adverse event	13 (5.5%)	10 (7.8%)
Death in the catheterisation lab	1 (0.4%)	0 (0.0%)

	Other procedures			
	Other vascular device/coil	Mitral/tricuspid valvuloplasty	Vascular/valvar perforations	RV biopsy
Number of cases	184	18	12	3372
Weight	17.4 [9.7, 51.0]	60.5 [30.0, 73.0]	3.7 [2.7, 4.0]	38.2 [18.6, 58.5]
Procedure time	139.0 [92.5, 186.0]	126.0 [97.0, 173.0]	112.5 [91.5, 136.5]	38.0 [22.0, 60.0]
Contrast	3.9 [2.7, 5.1]	0.9 [0.5, 1.2]	5.9 [4.6, 6.5]	0.2 [0.0, 0.7]
Any AE	19 (10.4%)	1 (5.6%)	5 (41.7%)	108 (3.2%)
Major AE	1 (0.5%)	1 (5.6%)	2 (16.7%)	20 (0.6%)
Death in the catheterisation lab	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

AE = adverse events; BAS = balloon atrial septostomy; IMPACT = IMproving Paediatric and Adult Congenital Treatment; MPA = main pulmonary artery; PA = pulmonary artery; PDA = patent ductus arteriosus; RV = right ventricle; VSD = ventricular septal defect

*The listed atrial septal interventions (of any type) include all the patients with all underlying diagnoses, whether transposition of the great arteries, hypoplastic left heart syndrome, or any other diagnosis

In this data set, the most commonly performed cases included many well-established case types such as pulmonary artery rehabilitation, right ventricular biopsy, collateral occlusion, as well as atrial septal interventions; however, it also included newer case types such as transcatheter pulmonary valve implantation, which was performed in almost 5% of "non-core" cases submitted to the IMproving Paediatric and Adult Congenital Treatment registry.

The incidence of any adverse events within the IMproving Paediatric and Adult Congenital Treatment registry among "non-core" cases was 12%, whereas major adverse events occurred in 1.4% of the cases. This lies within the range of adverse events reported for "core" interventional procedures, which ranged from 5.3 to 24.3% for any adverse events and from 0 to 3.3% for major adverse events, as reported by Moore et al.[10] It is important to note that the three of four case categories with the highest incidence of adverse events were among those least frequently performed ($n < 25$ cases), whereas four of the five case categories with the lowest incidence of adverse events were among those more frequently performed case categories ($n > 70$ cases).

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For diagnostic cases captured in the IMproving Paediatric and Adult Congenital Treatment registry, any adverse events occurred in 10% of the cases, whereas major adverse events occurred in 1.4% of the cases, as reported by Vincent et al.[13] Given the very wide variability of case types captured within the group of "non-core" procedures, it is impossible to derive any more detailed conclusions from this data, however.

In addition to IMproving Paediatric and Adult Congenital Treatment data, the only other recent multi-centre registry data available on catheterisation-related adverse events originate from the Congenital Cardiac Catheterization Project on Outcomes registry.[1] It reported an incidence of any adverse event of 20% for interventional cases, with 9% being high-severity adverse events; however, the definition of adverse events was broad and not limited to just a few selected types of adverse events, as is the case with the IMproving Paediatric and Adult Congenital Treatment registry. Importantly, however, the incidence of life-threatening adverse events reported from the Congenital Cardiac Catheterization Project on Outcomes registry (2.1%) was more similar to the incidence of major adverse events of 1.4% reported in the present study.[14]

Although the incidence of adverse events is difficult to compare between these two registries, all four case types of the IMproving Paediatric and Adult Congenital Treatment registry that had associated adverse events in >30% of cases had previously also been identified as high-risk "procedure type risk groups" by the data derived from the Congenital Cardiac Catheterization Project on Outcomes registry.[15] Further work has been completed on the IMproving Paediatric and Adult Congenital Treatment data set to develop a risk stratification and risk-adjustment method, and to compare this with the catheterisation for congenital heart disease adjustment for risk method derived from the Congenital Cardiac Catheterization Project on Outcomes data set, and these results will be forthcoming in the near future.[9] In addition, the procedural diversity shown in this report as well as the low rates of adverse events necessitate the development of a risk-adjustment methodology in IMproving Paediatric and Adult Congenital Treatment to allow for equitable comparisons among institutions in the future, work that is presently being completed within a focussed working group of the IMproving Paediatric and Adult Congenital Treatment registry.

Furthermore, one of the few case types that allowed comparison with recent data available from other registries was endomyocardial biopsy, which accounted for >40% of all "non-core" cases submitted to the IMproving Paediatric and Adult Congenital Treatment registry. Among the biopsy cases submitted to the IMproving Paediatric and Adult Congenital Treatment registry, the rate of any adverse event was 3.2% and major adverse events 0.6%. This is very similar to recent results reported from the Congenital Cardiac Catheterization Project on Outcomes registry collected from eight centres, which documented an overall adverse event rate of 3.3% with 1.1% of high-severity adverse events.[16] Median case times were 38 minutes for the biopsy data derived from the IMproving Paediatric and Adult Congenital Treatment registry and 30 minutes for the Congenital Cardiac Catheterization Project on Outcomes data.

Pulmonary artery rehabilitation, both proximal and peripheral, accounted for >10% of all "non-core" cases. Individual data were difficult to compare with other series, as most reports were single-centre experiences, with only the Congenital Cardiac Catheterization Project on Outcomes registry reporting a recent multi-centre experience.[7] Furthermore, the location of the intervention, proximal versus peripheral, as well as the number of interventions performed make it difficult to compare these data with other reports. Within the IMproving Paediatric and Adult Congenital Treatment data set, the incidence of any adverse event associated with pulmonary artery balloon angioplasty was 13.0% for proximal locations and 13.8% for peripheral locations, with major adverse events occurring in <1% of the cases. In contrast, the Congenital Cardiac Catheterization Project on Outcomes registry reported rates of high severity adverse events (level 3–5) for different types of balloon angioplasty between 9 and 14%;[7] however, it is important to point out that level 3–5 adverse events as reported in the Congenital Cardiac Catheterization Project on Outcomes registry do include many adverse events that would not be classified as a major adverse event in the IMproving Paediatric and Adult Congenital Treatment registry, and therefore comparison with life-threatening adverse events – only level 4 and level 5 – of the Congenital Cardiac Catheterization Project on Outcomes registry would be more appropriate.[14]

Limitations

Despite being a large study cohort including a total of 8021 cases, the number of cases within individual case types was frequently still small, thereby somewhat limiting the ability to draw any more stringent conclusions from the data presented for many of the case categories. Furthermore, outcome metrics, other than adverse events, have not been firmly established for any of the presented case types, and as such these data do not

allow for any conclusions relating to procedural efficacy; however, providing these data is crucial to aid establishing those metrics in the future. In addition, although attempts were made to present well-defined case types, the IMproving Paediatric and Adult Congenital Treatment registry does not collect some other important details such as whether multiple interventions of the same case category were performed in the same case in a given patient – for example, balloon angioplasty in a peripheral pulmonary artery branch in a single lesion would be categorised as the same case category in a case where five peripheral branches were treated through balloon angioplasty, which naturally would have an important impact on parameters such as, for example, case time. Other limitations of this study are inherent to the IMproving Paediatric and Adult Congenital Treatment registry itself, which includes, for example, the lack of longitudinal data collection. Comparison of adverse event data with other registries is often limited by very different definitions and inclusions of adverse events into the specific registries.

Conclusions

The IMproving Paediatric and Adult Congenital Treatment registry has provided important data on the frequency and spectrum of cardiac catheterisation procedures performed in the present era. For many procedures, more data and work are needed to identify more subtle differences between case categories, especially as it relates to the incidence of major adverse events, and to further develop a risk-adjustment methodology to allow equitable comparisons among institutions.

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Conflicts of Interest

None.

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