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Original Article

Procedural characteristics and adverse events in diagnostic and interventional catheterisations in paediatric and adult CHD: initial report from the IMPACT Registry

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Abstract *Objectives:* To report procedural characteristics and adverse events on data collected in the registry. *Background:* The IMPACT – IMproving Paediatric and Adult Congenital Treatment – Registry is a catheterisation registry of paediatric and adult patients with CHD undergoing diagnostic and interventional cardiac catheterisation. We are reporting the procedural characteristics and adverse events of patients undergoing diagnostic and interventional catheterisation procedures from January, 2011 to March, 2013. *Methods:* Demographic, clinical, procedural, and institutional data elements were collected at the participating centres and entered via either a web-based platform or software provided by American College of Cardiology-certified vendors, and were collected in a secure, centralised database. Centre participation was voluntary. *Results:* During the time frame of data collection, 19,797 procedures were entered into the IMPACT Registry. Procedures were classified as diagnostic only (35.4%); one of six specific interventions (23.8%); other or multiple interventions (40.7%); and were further broken down into four age groups. Anaesthesia was used in 84.1% of diagnostic procedures and 87.8% of interventional ones. Adverse events occurred in 10.0% of diagnostic and 11.1% of interventional procedures. *Conclusions:* The IMPACT Registry is gathering data to set national benchmarks for diagnostic and certain specific interventional procedures. We are seeing little differences in procedural characteristics or adverse events in diagnostic procedures compared with interventional procedures overall, but there is significant variation in adverse events amongst age categories. Risk stratification and patient acuity scores will be required for further analysis of these differences.

Kewords: IMPACT Registry; quality improvement; cardiac catheterisation

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The IMPACT – IMproving Paediatric and Adult Congenital Treatment – Registry is a catheterisation registry of all children and adults with CHD undergoing diagnostic and interventional cardiac catheterisation. Following discussions regarding the potential of this registry in 2006, a pilot project was launched in 2009 and the registry was implemented in December, 2010. As there were very few sites actually entering data in 2010, what follows is a report of data collected for nine

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quarters beginning in January, 2011 and ending in March, 2013.

Registry data are useful in identifying, amongst other things, benchmark metrics for success rates and complications for specific procedures. The complexity and diversity of congenital cardiac diagnoses makes it difficult to collect large numbers of similar procedures from any single centre. Single-centre data that are published often are skewed towards those centres with the best outcomes and/or larger centres. Although this may set a standard, it does not necessarily reflect care that is provided in the general community. The intent of the IMPACT Registry is to gather information from as many centres as possible performing diagnostic and interventional catheterisation procedures on all children and adults with CHD. It is hoped that through the registry we will benchmark performance, identify best practices, areas requiring improvement, and ultimately improve patient outcomes. As with other National Cardiovascular Data Registries, participation is voluntary and institutions need not submit data.

Previous congenital cardiac databases have concentrated mainly on interventional procedures.[1–8] In its design, the IMPACT Registry aims to collect catheterisation data on all children and adult congenital cases, including all diagnostic, biopsy, and interventional procedures. More in-depth data were obtained on the following six specific interventions: device closure of atrial septal defect; device closure of patent ductus arteriosus; pulmonary valvuloplasty for pulmonary stenosis; aortic valvuloplasty for aortic stenosis; interventions – angioplasty and stenting – on coarctation of the aorta; and central pulmonary artery stenting. An important difference between this registry and others is the inclusion of all catheterisation cases with unrestricted participation. During the development of the registry, the steering committee felt that diagnostic catheterisations should be separated from interventional ones, as they would be less complex. To test this hypothesis, data are presented for diagnostic-only procedures for comparison with interventional ones.

Methods

The IMPACT 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 has been previously described by Martin et al.[9] The Registry collects data for use in the development of performance and quality metrics, quality improvement programmes, and peer-reviewed outcome research focussed on children and adults with CHD, who are undergoing diagnostic catheterisations and catheter-based interventions. Demographic, clinical, procedural, and institutional data elements were collected at participating centres and entered via either a web-based platform or software provided by American College of Cardiology-certified vendors, and were collected in a secure, centralised database. The IMPACT Registry has in place a data quality programme consistent with that described for the IMPACT Registry®[10]. A comprehensive description of IMPACT Registry data elements and definitions is available at http://www.ncdr.com. The IMPACT Registry research studies are determined to meet the definition of research not requiring informed consent, as patient information is collected anonymously and without unique patient identifiers.

Data collection forms submitted to the National Cardiovascular Data Registry were analysed for completeness, and those with adequate information were used for the purposes of statistical analysis in the registry. The data are presented by quarter of event to identify the growth of the registry in terms of number of centres enrolled and number of events in a quarter and on a cumulative basis. This report focusses on general data for patients undergoing diagnostic cardiac catheterisation as well as interventional catheterisation procedures. Patients having one of the six specific interventions and those with multiple interventions or interventions other than the six specific ones were addressed in different reports.

Patients undergoing catheterisation procedures were divided into four age groups as follows:

Newborns: <30 days; Infants: ⩾30 days, ⩽1 year; Children: >1 year, ⩽18 years; Adults: >18 years.

For each age group, data for patients undergoing diagnostic and interventional catheterisations were analysed for the following major adverse events: need for a permanent or temporary pacemaker; cardiac arrest; tamponade requiring pericardial drainage); embolic stroke (within 72 hours); and unplanned cardiac surgery due to catheterisation complications.

Other adverse events also reported and analysed include the following: arrhythmias, including any arrhythmia as well as those requiring cardioversion or antiarrhythmic medication; new heart valve regurgitation; air embolus; device malposition or thrombus requiring surgery; device embolisation requiring retrieval by catheterisation or surgery; new requirement for dialysis; airway event requiring intubation; event requiring extracorporal membrane oxygenation; event requiring left ventricular assist device; bleeding event including bleeding event at access site, haematoma at access site, retroperitoneal bleeding, gastrointestinal bleeding, genital-urinary bleeding, and other bleeding; red blood cell or whole blood transfusion; other events; unplanned vascular surgery; and unplanned other surgeries and subsequent cardiac catheterisations.

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Adverse events are reported if they occur within 30 days after the procedure, except for embolic stroke, bleeding events, and transfusions, which are reported only within 72 hours following the procedure. Bleeding events are characterised as follows: haemoglobin drop of ⩾3 g/dl; transfusion of whole blood or packed red blood cells; procedural intervention/surgery at the bleeding site to reverse/stop or correct the bleeding, such as surgical closures/exploration of the arteriotomy site, balloon angioplasty to seal an arterial tear, and endoscopy with cautery of a gastro-intestinal bleed. If a subsequent catheterisation occurs before the time limit for collecting adverse events, future events are attributed to the subsequent catheterisation.

Adverse events are not necessarily caused by the catheterisation procedure itself as other events, including surgery, may have occurred between catheterisation and the adverse event. Adverse events are reported as a percentage of patients in each age group who have an event during or after a catheterisation procedure, whereas the number of deaths is reported/episode of care. Deaths are dealt with separately, and like the other adverse events the data indicate only that mortality occurred during the admission and not that it is necessarily attributable to the catheterisation procedure itself.

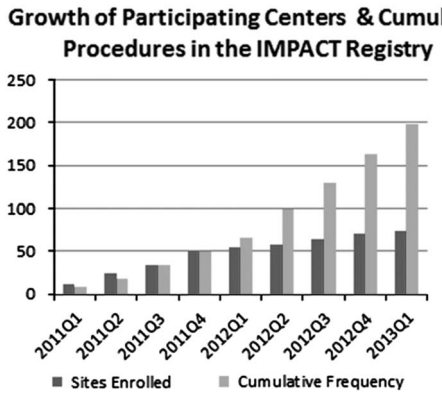

Figure 1.
Growth of the IMPACT Registry by number of participating centres per quarter and cumulative number of cases over time (times 100).

Descriptive statistics for catheterisation procedures are presented. All the categorical variables are reported as frequency and/or percentage and they are compared among age groups using the χ^2 test or Fisher's exact test. All the results including the group comparison and the odds ratios are based on univariate analyses. All statistical analyses were conducted using SAS Version 9.3 (SAS Institute, Cary, North Carolina, United States of America).

Results

Registry participation has grown from 12 sites (Q1 2011) to 73 sites (Q1 2013). Currently there are 91 sites in the IMPACT Registry. Along with the growing number of sites, the total number of event submissions has increased from 848 (Q1 2011) to 19,797 (Q1 2013) (Fig 1).

Of the 19,797 procedures analysed in the registry, 7010 (35.4%) procedures were for diagnostic "only" catheterisations; 23.8% of the procedures were for one of the specific six isolated interventions being evaluated; and 40.7% of the procedures were for "other" reasons. These include endomyocardial biopsies, interventions other than the six cited – for example, pulmonary artery angioplasty – and multiple procedures – for example, atrial septal defect device closure and patent ductus arteriosus occlusion during the same procedure, or a pulmonary artery stent as well as peripheral pulmonary artery dilations (Table 1).

Tables 2a and b summarise the results of data collected on procedural status, sedation, and adverse events for diagnostic-only and interventional procedures. Table 2c compares the same data elements of the two groups. There were some differences in procedural status and sedation with interventional cases being more elective and more likely to use anaesthesia support.

Table 1. All procedures are categorised by age group and procedure type.

	Total	Newborn	Infant	Child	Adult
n	19,797	1247 (6.3%)	3808 (19.2%)	11,580 (58.5%)	3162 (16%)
Diagnostic	7010 (35.4%)	457 (36.6%)	1759 (46.2%)	3554 (30.7%)	1240 (39.2%)
Atrial septal defect	1362 (6.9%)	2 (0.2%)	19 (0.5%)	999 (8.6%)	342 (10.8%)
Coarctation	671 (3.4%)	12 (1.0%)	267 (7.0%)	300 (2.6%)	92 (2.9%)
aortic valve	340 (1.7%)	103 (8.3%)	81 (2.1%)	128 (1.1%)	28 (0.9%)
Pulmonary valve	661 (3.3%)	202 (16.2%)	244 (6.4%)	181 (1.6%)	34 (1.1%)
Patent ductus arteriosus	1375 (6.9%)	10 (0.8%)	359 (9.4%)	962 (8.3%)	44 (1.4%)
Pulmonary artery stent	320 (1.6%)	7 (0.6%)	53 (1.4%)	226 (2.0%)	34 (1.1%)
Other	8058 (40.7%)	454 (36.4%)	1026 (26.9%)	5230 (45.2%)	1348 (42.6%)

Procedures categorised by age group and procedure type. Percentages refer to the percentage of the specific procedure type compared with the total number of procedures or total for that age group

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Table 2a. Procedural characteristics and adverse events for patients having a diagnostic catheterisation.

Diagnostic-only procedures	Total (7010) (n)	Newborn (457) (%)	Infant (1759) (%)	Child (3554) (%)	Adult (1240) (%)	p value
Procedure status						<0.001
Elective	5799	35.2	72.6	92.5	89.8	
Urgent	1000	50.1	25.2	6.3	9.1	
Emergency	153	13.8	2.2	1.1	1.1	
Salvage	6	0.9	0	0.1	0	
Anaesthesiologist present	5872	85.9	88.3	88.3	65.2	<0.001
anaesthesiologist called in	14	0	1	1.5	1.5	0.975
Sedation						<0.001
General anaesthesia	5261	82.2	85.4	80.1	45.7	
Epidural	7	0	0.2	0.1	0.1	
Caudal	4	0	0.1	0.1	0.1	
IV	1597	17.3	13.5	18	52.1	
IM	3	0	0.1	0	0.2	
Oral intranasal	17	0	0.1	0.3	0.3	
None	82	0.2	0.6	1.4	1.6	
Arrhythmia	200	11.1	3.6	1.6	2.3	<0.001
Arrhythmia requiring cardioversion	52	28	17.7	22.4	48.3	0.017
Arrhythmia requiring antiarrhythmic medication	91	42	52.4	48.3	32.1	0.303
Arrhythmia requiring permanent pacemaker	5	4	1.6	0	6.9	0.123
Arrhythmia requiring temporary pacemaker	23	14	9.7	10.3	13.8	0.854
Cardiac arrest	67	2.7	1.6	0.6	0.5	<0.001
New heart valve regurgitation	1	0	0	0	0	1
Tamponade	4	0.2	0	0	0.2	0.004
Air embolus	4	0.2	0.1	0	0	0.125
Embolic stroke	3	0	0.1	0	0.1	0.125
Device malposition or thrombus (Requiring surgery)	1	0.2	0	0	0	0.065
Device embolisation (requiring device retrieval)	2	0	0	0	0.2	0.059
Device embolisation retrieved via catheterisation	2				100	
Device embolisation retrieved via surgery	0	0	0	0	0	
New requirement for Dialysis	5	0.9	0	0	0.1	<0.001
Airwav event requiring intubation	39	1.1	0.7	0.5	0.2	0.045
Event requiring ECMO	20	1.6	0.3	0.2	0.2	<0.001
Event requiring LVAD	0	0	0	0	0	
Bleeding event	74	1.6	0.6	1.1	1.4	0.071
Bleeding event at access site	30	42.9	30	50	23.5	0.266
Haematoma at access site	39	28.6	33.3	65	47.1	0.133
Retroperitoneal bleeding	4	14.3	12.5	2.6	6.3	0.224
Gastrointestinal bleeding	4	14.3	25	0	6.3	0.018
Genital-urinary bleeding	1	0	12.5	0	0	0.214
Other bleeding	13	14.3	25	12.8	31.3	0.352
RBC/whole blood transfusion	282	16.5	8.8	1.2	1.1	<0.001
Other events	136	4.2	2.6	1.4	1.8	<0.001
Planned cardiac surgery	804	30.7	20.2	6.9	5.7	<0.001
Unplanned cardiac surgery	20	1.1	0.4	0.1	0.3	0.003
Unplanned vascular surgery	2	0	0.1	0	0	0.153
Unplanned other surgery	44	2.4	1.2	0.2	0.4	<0.001
Subsequent cardiac cath	20	0.9	0.3	0.2	0.3	0.056
Any adverse event	691	30.9	16.3	5.5	6.3	<0.001
Major adverse events	98	4.7	2.1	0.7	1.4	<0.001

ECMO = extracorporeal membrane oxygenation; IM = intramuscular; IV = intravenous; LVAD = left ventricular assist devices; RBC = red blood cells
Arrhythmias and bleeding events are subcategorised. Results are shown as the total for the cohort and broken down into age categories Percentages refer to the percent within the age group

Major adverse events not including death occurred in 1.4% of diagnostic catheterisation procedures, (major adverse event/catheterisation lab visit), and in 1.2% of interventional procedures. Major adverse events were most common in neonates (4.7% of diagnostic catheterisation; 4.2% of interventional

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Table 2b. Procedural characteristics and adverse events for patients having an interventional catheterisation.

Interventional procedures	Total (12,787) (n)	Newborn (790) (%)	Infant (2049) (%)	Child (8026) (%)	Adult (1922) (%)	p value
Procedure Status						<0.001
Elective	11,020	24.9	74.2	93.7	94.4	
Urgent	1388	52.6	22.4	5.3	5.0	
Emergency	304	20.3	3.0	0.9	0.6	
Salvage	34	2.2	0.4	0.1	0.1	
Anaesthesiologist present	11,219	89.4	93.2	90.2	71.3	<0.001
anaesthesiologist called in	40	2.5	4.5	2.6	2.5	0.6
Sedation						
General anaesthesia	10,203	88.3	92.1	82.4	53.6	
Epidural	10	0.0	0.0	0.1	0.1	
Caudal	4	0.0	0.0	0.0	0.1	
IV	2259	10.4	7.4	15.0	42.9	
IM	4	0.0	0.0	0.0	0.1	
Oral/intranasal	20	0.0	0.1	0.2	0.1	
None	253	1.3	0.3	2.2	3.1	
Arrhythmia	273	7.1	2.9	1.4	2.2	<0.001
Arrhythmia requiring cardioversion	75	35.7	25.4	21.6	35.7	0.138
Arrhythmia requiring antiarrhythmic medication	119	55.4	45.8	41.4	31.0	0.101
Arrhythmia requiring permanent pacemaker	1	0.0	0.0	0.9	0.0	1
Arrhythmia requiring temporary pacemaker	23	5.4	5.1	9.5	14.3	0.331
Cardiac arrest	91	2.7	1.4	0.4	0.4	<0.001
New heart valve regurgitation	18	1.1	0.2	0.0	0.1	<0.001
Tamponade	21	1.1	0.2	0.1	0.1	<0.001
Air embolus	4	0.0	0.0	0.0	0.0	0.841
Embolic stroke	8	0.0	0.1	0.1	0.1	0.917
Device malposition or thrombus (requiring surgery)	17	0.1	0.2	0.1	0.1	0.608
Device embolisation (requiring device retrieval)	69	0.3	0.4	0.6	0.6	0.643
Device embolisation retrieved via catheterisation	51	50.0	77.8	73.9	75.0	0.871
Device embolisation retrieved via surgery	12	50.0	11.1	15.2	25.0	0.38
New requirement for dialysis	11	0.1	0.0	0.1	0.3	0.029
Airway event requiring intubation	79	2.2	1.0	0.4	0.6	<0.001
Event requiring ECMO	35	1.5	0.7	0.1	0.0	<0.001
Event requiring LVAD	0	0.0	0.0	0.0	0.0	
Bleeding event	206	1.7	1.5	1.5	2.1	0.265
Bleeding event at access site	106	30.8	33.3	56.2	60.0	0.038
Hematoma at access site	77	23.1	30.0	44.6	26.8	0.1
Retroperitoneal bleeding	7	7.7	0.0	1.7	10.0	0.043
Gastrointestinal bleeding	3	7.7	3.6	0.9	0.0	0.109
Genital-urinary bleeding	2	0.0	0.0	0.0	5.0	0.11
Other bleeding	38	53.8	41.4	12.1	12.5	<0.001
RBC/whole blood transfusion	544	17.6	12.9	1.4	1.5	<0.001
Other events	366	5.6	4.5	2.2	2.7	<0.001
Planned cardiac surgery	403	19.0	5.6	1.6	0.6	<0.001
Unplanned cardiac surgery	47	1.1	0.6	0.2	0.4	<0.001
Unplanned vascular surgery	14	0.1	0.2	0.1	0.2	0.285
Unplanned other surgery	38	1.5	0.3	0.2	0.1	<0.001
Subsequent cardiac cath	37	0.5	0.2	0.3	0.3	0.621
Any adverse event	1414	30.2	20.8	7.3	9.0	<0.001
Major adverse events	157	4.2	1.9	0.8	1.1	<0.001

ECMO = extracorporeal membrane oxygenation; IM = intramuscular; IV = intravenous; LVAD = left ventricular assist devices; RBC = red blood cells
Arrhythmias and bleeding events are subcategorised. Results are shown as the total for the cohort and broken down into age categories. Percentages refer to the percent within the age group

procedures) with decreasing prevalence in infants (2.1% diagnostic versus 1.9% of interventional procedures). Adult patients had a significantly higher prevalence of major adverse events (1.4% of diagnostic versus 1.1% of interventional procedures) than children and adolescents (0.7:0.8%,) (Tables 2a

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Table 2c. Procedural characteristics and adverse events for patients having a diagnostic catheterisation compared with an interventional one.

	Diagnostic procedures (7010) (n)	%	Interventional procedures (12,787) (n)	%	p value
Procedure status					<0.001
Elective	5799	83.3	11,020	86.5	
Urgent	1000	14.4	1388	10.9	
Emergency	153	2.2	304	2.4	
Salvage	6	0.1	34	0.3	
Anaesthesiologist present	5872	84.1	11,219	87.8	<0.001
anaesthesiologist called in	14	1.3	40	2.7	0.016
Sedation					<0.001
General anaesthesia	5261	75.5	10,203	80.0	
Epidural	7	0.1	10	0.1	
Caudal	4	0.1	4	0.0	
IV	1597	22.9	2259	17.7	
IM	3	0	4	0.0	
Oral intranasal	17	0.2	20	0.2	
None	82	1.2	253	2.0	
Arrhythmia	200	2.9	273	2.1	0.001
Arrhythmia requiring cardioversion	52	26.1	75	27.5	0.745
Arrhythmia requiring antiarrhythmic medication	91	45.7	119	43.6	0.644
Arrhythmia requiring permanent pacemaker	5	2.5	1	0.4	0.087
Arrhythmia requiring temporary pacemaker	23	11.6	23	8.4	0.257
Cardiac arrest	67	1	91	0.7	0.062
New heart valve regurgitation	1	0	18	0.1	0.006
Tamponade	4	0.1	21	0.2	0.043
Air embolus	4	0.1	4	0.0	0.465
Embolic stroke	3	0	8	0.1	0.757
Device malposition or thrombus (requiring surgery)	1	0	17	0.1	0.008
Device embolisation (requiring device retrieval)	2	0	69	0.5	<0.001
Device embolisation retrieved via catheterisation	0	0	51	73.9	1
Device embolisation retrieved via surgery	0	0	12	17.4	1
New requirement for dialysis	5	0.1	11	0.1	0.724
Airway event requiring intubation	39	0.6	79	0.6	0.605
Event requiring ECMO	20	0.3	35	0.3	0.871
Event requiring LVAD	0	0	0	0.0	
Bleeding event	74	1.1	206	1.6	0.002
Bleeding event at access site	30	40.5	106	52.0	0.092
Haematoma at access site	39	53.4	77	37.6	0.018
Retroperitoneal bleeding	4	5.7	7	3.5	0.485
Gastrointestinal bleeding	4	5.7	3	1.5	0.08
Genital-urinary bleeding	1	1.4	2	1.0	1
Other bleeding	13	18.6	38	19.2	0.909
RBC/whole blood transfusion	282	4.1	544	4.3	0.473
Other events	136	1.9	366	2.9	<0.001
Planned cardiac surgery	804	11.5	403	3.2	<0.001
Unplanned cardiac surgery	20	0.3	47	0.4	0.348
Unplanned vascular surgery	2	0	14	0.1	0.056
Unplanned other surgery	44	0.6	38	0.3	<0.001
Subsequent cardiac cath	20	0.3	37	0.3	0.972
Any adverse event	691	10	1414	11.1	0.013
Major adverse events	98	1.4	157	1.2	0.289

ECMO = extracorporeal membrane oxygenation; IM = intramuscular; IV = intravenous; LVAD = left ventricular assist devices; RBC = red blood cells
Arrhythmias and bleeding events are subcategorised

and b). These differences in major adverse events among age groups were statistically significant (p value < 0.001). Any adverse event occured in 10.0% of diagnostic procedures and 11.1% of interventional cases (p = 0.013), also being particularly prevalent in newborns and infants (Tables 2a–c).

Vascular access: venous access sites other than femoral were reported in 12.8% of diagnostic cases

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and 22% of interventional ones. Non-femoral arterial access was used in 2.3% of diagnostic cases – 0.34% using the umbilical artery – and 1.8% of interventional procedures – 0.38% using the umbilical artery. Analysing the use of non-femoral or umbilical arterial access, the carotid artery is most commonly used in newborns, infants, and children (97 procedures carotid, 31 radial), while the radial artery is used most commonly in adults (7 carotid, 62 radial).

All cause hospital mortality for patients having a catheterisation during their admission was 2.1%; 12.0% for newborns, 4.6% infants, 0.7% children, and 0.8% adults based on available data in 18,956 hospital admissions with the discharge status known (Table 3). Of the 395 deaths reported, 16 occurred in the catheterisation laboratory at the time of the procedure; 20.3% of patients who ultimately died, died within 3 days following the; procedure; 63.5% died after 7 days, with 43% of these patients dying after 2 weeks or more following the last catheterisation procedure (Table 4). The primary cause of death is listed in Table 4. Cardiac causes account for 58.7% of deaths with pulmonary causes another 17.7% (Table 5). The IMPACT Registry currently does not account for other procedures – for example, cardiac and non-cardiac surgical procedures – which might have occurred either before or after a catheterisation procedure, making attribution of death or AE to the catheterisation difficult.

Of the potential risk factors and genetic syndromes that might have contributed to adverse events and poor outcomes, only diabetes mellitus, renal insufficiency, seizure disorder, and single ventricle were statistically associated with risk of a major adverse event. Genetic syndromes were not associated with any increased risk of a major adverse event.

Discussion

This harvest of over 2 years of data collection demonstrates some of the trends we previously suspected. Diagnostic catheterisations now account for approximately only one-third of all procedures. This is similar to data reported by others.[6] Previous reports have focussed on procedural characteristics and adverse events of interventional procedures. As IMPACT collects data on all procedures, we are able to separate diagnostic procedures from the interventional ones. What we are seeing, however, is little difference in characteristics or adverse events between the two groups, although there are significant differences in adverse events between age groups.

Anaesthesiology support is being used in the majority of cases in most institutions, 84.1% for diagnostic procedures and 87.8% for interventional ones. This may be due to a combination of operator preference as well as hospital and national sedation policies, but regardless of why the support is used, the rate of airway events requiring intubation is <1%.

Although vascular access is still predominately from the femoral approach, non-femoral sites for venous access are used in 12.8% of diagnostic and 22% of interventional cases. Non-femoral arterial access is low with the carotid artery often being preferred in children compared with the radial artery in adults. As vascular access issues are not necessarily known before undertaking the catheterisation procedure, this may question whether physicians performing these procedures should be versed in more than just femoral access techniques.

Major adverse events are relatively uncommon (1.4% of diagnostic, 1.2% of interventions), but are highest in the newborn age group. Adverse events occurred in 10.0% of diagnostic cases and 11.1% of interventional cases. Reports of adverse event rates

Table 3. Categorisation of death during the episode of care.

All cases	Total	Newborn	Infant	Child	Adult	p value
Episodes of care	18,956	1129	3438	11,283	3106	
Discharge status						
Alive	18,561	994	3281	11,205	3081	
Dead	395	135	157	78	25	
% of patients with outcome of death	2.1	12	4.6	0.7	0.8	<0.001
Death in the cath lab	16	6	3	4	3	0.083

Table 4. Time from catheterisation to death.

	0–1 day	1–2 days	2–3 days	3–7 days	7–14 days	>14 days	Total
Number of deaths	26	20	34	64	81	170	395
% of deaths	6.6	5.1	8.6	16.2	20.5	43	100

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Table 5. Primary cause of death.

Primary Cause of Death	Total	Newborn	Infant	Child	Adult
Cardiac	149 (65.1%)	62 (76.5%)	61 (58.1%)	17 (53.1%)	9 (81.8%)
Neurologic	5 (2.2%)	1 (1.2%)	2 (1.9%)	2 (6.3%)	0 (0.0%)
Renal	2 (0.9%)	1 (1.2%)	1 (1.0%)	0 (0.0%)	0 (0.0%)
Vascular	1 (0.4%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Infection	7 (3.1%)	3 (3.7%)	3 (2.9%)	1 (3.1%)	0 (0.0%)
Valvular	1 (0.4%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pulmonary	38 (16.6%)	5 (6.2%)	26 (24.8%)	6 (18.8%)	1 (9.1%)
Unknown	6 (2.6%)	1 (1.2%)	4 (3.8%)	1 (3.1%)	0 (0.0%)
Other	20 (8.7%)	6 (7.4%)	8 (7.6%)	5 (15.6%)	1 (9.1%)

vary widely and range from 20%[11] for any adverse event to 1.9–7.4% for different institutions when comparing high-severity adverse events [7]. Given the different definitions and methodologies used, it is not possible to compare results, but it would appear that the results of this multi-institutional registry are within range of other reports.

The IMPACT® Registry in its current form is unable to attribute adverse events to the catheterisation procedure or other factors. This is particularly true for death before discharge. The mortality discussed is all cause mortality during the episode of care and is not necessarily attributable to the catheterisation procedure. Death is accounted for only as an event in the catheterisation laboratory or as the discharge status of the patient, regardless of other events, such as surgery, occurring during the hospital stay. Table 5 shows that nearly 80% of reported deaths occurred >72 hours after the catheterisation procedure. The fact that mortality risk is associated with patient age but not procedural factors (intervention versus diagnostic) strongly suggests that much of mortality risk is due to patient factors rather than the catheterisation procedure. Nonetheless, we believe that these data do portray a realistic picture of the overall mortality risk faced by patients requiring a cardiac catheterisation.

This first harvest of data has revealed several issues pertinent to the next version of the registry. As there are few differences in procedural characteristics and adverse events in diagnostic compared with interventional procedures, it is clear that a model of procedural complexity and risk stratification will be necessary to understand procedural risk and compare results. The current list of adverse events, major adverse events, and co-morbidities need revision. They were initially adopted from the National Cardiovascular Data Registry for Percutaneous Catheter Interventions, and although they provided a starting point they failed to capture some of the differences and definitions of paediatric problems compared with those seen in adults. The intimate relationship of congenital cardiac catheterisation and surgery, with surgery often occurring shortly after a catheterisation procedure, will be addressed in the next version of IMPACT. Currently, adverse events are captured for 72 hours to 30 days, depending on the event, following the catheterisation procedure or terminated with the next catheterisation procedure or discharge. With the revision of the registry, the next surgical procedure will be included as a stopping point for capturing catheterisation-related events, unless the surgical procedure is a result of a catheter complication. The intent of the registry as constructed was to capture adverse events that impact patient care; however, the consequence of this approach is the difficulty in attributing those events to the catheterisation procedure. Attribution can be very subjective and may vary widely from centre to centre, particularly for patients who have long hospital stays unrelated to a catheterisation procedure. We hope to institute a shorter window of time for collecting adverse events post-procedure, as this may be seen by the operators as more likely being related, or possibly related, to the catheterisation procedure, thus driving quality improvement while at the same time allowing for more consistent input of data from all centres.

Finally, although data collection is currently limited to hospital discharge, we hope to extend this to long-term follow-up for some specific procedures with future versions.

The intent of the IMPACT Registry is to gather data to set national benchmarks for diagnostic and certain specific interventional procedures. Future versions of IMPACT will address risk stratification, attribution of adverse events, and long-term follow-up of some interventions. Our hope is that the information generated will allow creation of recommendations to guide improvements in catheter intervention. Although adverse events as currently reported are not completely attributable to the catheterisation procedure itself, it is clear that newborns and infants who require a catheterisation procedure are at much higher risk for adverse events, including death, during their hospital admission than are older patients.

Although the IMPACT Registry was conceived and implemented to improve catheterisation outcomes, it

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should be stated unequivocally that, as currently constructed, centre-specific IMPACT data are not yet ready for comparisons between centres. Until risk adjustment and case complexity are available along with validated auditing and adjudication procedures, any attempt to compare variances between centres should be considered premature. First and foremost, the data reflect global events during an episode of care (hospital stay), not just what happens during, or as a consequence of, the index procedure. The data do, however, allow centres to look at their specific reports, and in a broad sense compare themselves to aggregate data. What may appear as a higher rate of major adverse events or death may be a case selection rather than a quality issue, some referral centres taking on cases others would not. These issues are not unique to IMPACT but are a growing concern amongst all registries, especially those requiring public reporting. It is, therefore, paramount that future versions of IMPACT address these issues.

Limitations of this report reflect current limitations of the IMPACT Registry. The data presented here were self-reported by centres and not audited, although there is currently a pilot audit project being performed. As mentioned above, there is no attribution of adverse events to the procedure, case complexity, or risk adjustment, making inter-institutional comparisons difficult.

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Conflicts of Interest

None.

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