

Original Article

Report from The International Society for Nomenclature of Paediatric and Congenital Heart Disease: cardiovascular catheterisation for congenital and paediatric cardiac disease (Part 2 – Nomenclature of complications associated with interventional cardiology)

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Abstract Interventional cardiology for paediatric and congenital cardiac disease is a relatively young and rapidly evolving field. As the profession begins to establish multi-institutional databases, a universal system of nomenclature is necessary for the field of interventional cardiology for paediatric and congenital cardiac disease. The purpose of this paper is to present the results of the efforts of The International Society for Nomenclature of Paediatric and Congenital Heart Disease to establish a system of nomenclature for cardiovascular catheterisation for congenital and paediatric cardiac disease, focusing both on procedural nomenclature and the nomenclature of complications associated with interventional cardiology. This system of nomenclature for cardiovascular catheterisation for congenital and paediatric cardiac disease is a component of The International Paediatric and Congenital Cardiac Code. This manuscript is the second part of the two-part

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series. Part 1 covered the procedural nomenclature associated with interventional cardiology as treatment for paediatric and congenital cardiac disease. Part 2 will cover the nomenclature of complications associated with interventional cardiology as treatment for paediatric and congenital cardiac disease.

Keywords: Adverse events; databases; cardiac nomenclature; complications; congenital heart disease; interventional cardiology

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INTERVENTIONAL CARDIOLOGY FOR PAEDIATRIC AND congenital cardiac disease is a relatively young and rapidly evolving field. A common system of nomenclature for interventional cardiology is imperative, particularly as we go beyond evaluating our individual practice to establishing multi-institutional and multi-national databases.¹⁻⁵ The purpose of this two-part series of manuscripts is to present the version of nomenclature of The International Paediatric and Congenital Cardiac Code updated to include a new system of nomenclature for cardiovascular catheterisation for congenital and paediatric cardiac disease, focusing both on procedural nomenclature and the nomenclature of complications associated with interventional cardiology.

This manuscript is the second part of a two-part series. Part 1 covered the procedural nomenclature associated with interventional cardiology as treatment for paediatric and congenital cardiac disease.⁶ Part 2 will cover the nomenclature of complications associated with interventional cardiology as treatment for paediatric and congenital cardiac disease. These two “companion” papers are designed to be read together. Specific complications related to transcatheter procedures involving arrhythmias, such as ablation and procedures involving pacemakers, are not included in this paper; these complications related to transcatheter procedures involving arrhythmias have already been discussed somewhat in prior publications from our group¹ and likely will be addressed further in additional publications from our group. In order to place these papers in perspective, Part 1 begins with a brief summary of the history and current status of The International Paediatric and Congenital Cardiac Code and the IMPACT RegistryTM (IMproving Pediatric and Adult Congenital Treatment) of the National Cardiovascular Data Registry[®].

The creation of a comprehensive listing of complications associated with interventional cardiology as treatment for paediatric and congenital cardiac disease is crucial because of the increasing interest in the benchmarking and establishment of outcomes for these treatments. A critical component in the determination of outcomes after cardiac catheterisation is a comprehensive list of complications to serve as the basis for establishment of benchmarks related to the safety of patients. Using

the process developed by The International Society for Nomenclature of Paediatric and Congenital Heart Disease during the creation of The International Paediatric and Congenital Cardiac Code, we describe the development of a comprehensive effort to develop a list of complications for the procedures associated with congenital cardiac catheterisation.

Methodology of the development of the list of complications of The International Paediatric and Congenital Cardiac Code

The basis for this long list of complications originated with the use of the structure and crossmap of terms developed by The International Society for Nomenclature of Paediatric and Congenital Heart Disease during the creation of The International Paediatric and Congenital Cardiac Code.⁷⁻¹² The list was further refined by taking advantage of two large ongoing studies of outcomes after paediatric and congenital cardiac catheterisation in the United States of America⁵: The Congenital Cardiac Catheterization Outcomes Project (C3PO)¹³ and the Mid-Atlantic Group of Interventional Cardiology (MAGIC).¹⁴ This process allowed for the addition of further codes drawn from the experience of multiple cardiologists. In total, 329 codes of complications associated with congenital cardiac catheterisation were developed along with 166 codes for associated modifiers. The list of codes was particularly enhanced by incorporating the structure for modifiers used in the Congenital Cardiac Catheterization Outcomes Project for the following five variables (the first three of these variables are related to “process” and the last two of these variables are related to “outcome”):

- the relationship of the complication to a specific component of the procedure (such as related to the administration of sedation: “Sedation related”, or related to the dilation component of the procedure: “Dilation related”, etc.),
- the timing of the complication (in or out of the catheterisation laboratory, before access, after removal of sheaths, etc.),
- the preventability of the complication,
- the outcome of the complication, and
- the severity of the complication (none to catastrophic).

Results

Using the International Paediatric and Congenital Cardiac Code and the hierarchical structure of the International Congenital Heart Surgery Nomenclature and Database Project of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons, codes for complications are broken down into main categories (Table 1) and then expanded in further detail beneath each branch level. For example, if tricuspid insufficiency is present after transcatheter closure of an atrial septal defect, the term "Trauma" is chosen from the level 2 of the hierarchy (Table 1), followed by the more detailed anatomic descriptor, "Heart valve", and the specific complication "Tricuspid valve insufficiency, New onset". Fully coded, this complication appears as:

"Cardiac catheterization, Complication, Trauma, Heart valve, Tricuspid valve insufficiency, New onset".

This complication equates to the following numerical codes and mapped terms in the version of The International Paediatric and Congenital Cardiac Code derived from the European Paediatric Cardiac Code of the Association for European Paediatric Cardiology:

Traumatic damage to heart valve during cardiovascular catheterisation procedure	15.50.20
Post-procedural tricuspid regurgitation	15.11.04
New onset	Q1.40.31

This example illustrates how either version of The International Paediatric and Congenital Cardiac Code can be used by individual institutions for use in comparisons of outcomes. The complete lists

Table 1. Complication code hierarchy main categories (level 2).

Arrhythmias
Respiratory
Haemodynamics
Metabolic
Neurologic
Infection
Renal
Gastrointestinal
Trauma
Equipment
Device or intervention
• Stent
• Device
• Dilation
• Coil
• Access
• Biopsy
• Foetal procedure
Embolism

of codes for complications associated with cardiovascular catheterization for congenital and paediatric cardiac disease, as laid out in the two versions of The International Paediatric and Congenital Cardiac Code described above, are available for free download at <http://www.IPCCC.net>. These lists are also available as electronic tables from the Cardiology in the

Table 2. Complication code qualifiers for relationship or attributability.

Catheterisation related
Related to catheter manipulation
Access related
Anaesthesia related
Sedation related
Dilation related
Valvotomy related
Stent related
Coil related
Device related
Biopsy related
Not related to catheterisation
Pre-existing condition

Table 3. Complication code qualifiers for timing.

Before entering catheterisation laboratory
In catheterisation laboratory
Before obtaining access
After sheaths inserted
After sheaths removed or case completed
During cardiovascular catheterisation procedure
Angiography
Balloon inflation
Stent deployment
Stent dilation
Device release
Retrieval of embolised device
Wire manipulation
During catheterisation sheath exchange
After catheterisation procedure before discharge
In recovery room
In intensive care unit
On general hospital ward
After discharge from hospital
New onset

Table 4. Complication code qualifiers for preventability and definitions.

Preventable: events where definite breach of standard technique was identified; necessary precautions were not taken; event was preventable by modification of technique or care.

Possibly preventable: events where definite breach of standard technique was not identified but may have occurred; necessary precautions may not have been taken; event may have been preventable by modification of technique or care.

Not preventable: events where no obvious breach of standard technique occurred; necessary precautions were taken; no clearly known alteration in method or care exists to prevent the event.

Young Website at <http://journals.cambridge.org/action/displayJournal?jid=CTY>.

After coding a complication as described above, qualifiers for process and outcome subsequently are added as shown in Tables 2, 3, 4, and 5. The qualifiers for process include qualifiers for relationship, timing, and preventability. These qualifiers for process were developed, in part, to understand where, in the process of the procedure, the complication occurred. First, the qualifiers for process include qualifiers to document the

relationship to a defined portion of the procedure, such as related to access, or related to placement of a device (such as, in the example above, an atrial septal defect occluder resulting in tricuspid insufficiency). Second, a complication is coded for the timing of the complication, such as “after sheaths inserted” or “with device release”, etc. Third, a qualifier for process is chosen to address the “preventability” of the complication.

Finally, qualifiers for outcome are also chosen for each complication. These qualifiers for outcome can

Table 5. Complication code qualifiers for severity and definitions.

Severity level 1: None

No harm, no change in condition, may have required monitoring to assess for potential change in condition with no intervention indicated
Example:

- Air embolus or balloon rupture with no symptoms or interventions

Severity level 2: Minor

Transient change in condition, not life-threatening, condition returns to baseline, required monitoring, required minor intervention such as holding a medication (withholding a medication or, in other words, not administering a medication that was scheduled or planned to be given), or obtaining laboratory test(s)

Examples:

- Transfusion of blood for procedural loss of blood or management of the haemodynamics of the patient
- Transient arrhythmias that do not require intervention or terminate with manipulation of a catheter
- Vascular injury that does not result in significant extravasation or loss of distal flow, and for which no interventions are performed
- Heparin therapy for loss of pulse
- Volume to support haemodynamics
- Intensive care unit for routine post-catheterisation care and monitoring, elective mechanical ventilatory support
- Successful snaring of embolized or malpositioned coil

Severity level 3: Moderate

Transient change in condition may be life-threatening if not treated, condition returns to baseline, required monitoring, required intervention such as reversal agent, additional medication, transfer to intensive care unit for monitoring, or moderate transcatheter intervention to correct condition

Examples:

- Additional access to manage technical complication, uneventful removal of a device, or expansion of a stent in non-obstructive location
- Haemodynamically stable arrhythmias requiring medication administration or cardioversion
- Vascular injury that results in significant extravasation or loss of distal flow, and requires catheter-based intervention to contain extravasation or restore flow
- Apnea, hypoxia, laryngospasm with conscious sedation requiring intubation
- Dopamine, epinephrine, calcium, in response to low blood pressure
- Atropine for heart block

Severity level 4: Major

Change in condition, life-threatening if not treated, change in condition may be permanent, may have required intensive care unit admit or emergent readmit to hospital, may have required invasive monitoring, required interventions such as electrical cardioversion or unanticipated intubation or required major invasive procedures or trans-catheter interventions to correct condition.

Examples:

- Haemodynamically unstable arrhythmias requiring DC (direct current) cardioversion or cardiopulmonary resuscitation
- Vascular damage which is life-threatening, results in significant extravasation or reduction of distal blood flow, requires major intervention to control extravasation or restore flow, or in which treatment does not restore flow or results in permanent significant reduction in distal flow after treatment
- Emergent surgery or heart lung bypass support (extracorporeal membrane oxygenation) to prevent death with successful recovery and wean from bypass support

Severity level 5: Catastrophic

Any complication associated with subsequent death

Complication severity level not determined

provide more information about a complication. For example, the complication of "Metabolic acidosis" can be followed by the final outcome, such as "Resolved, Spontaneously". The final qualifier for outcome is for the severity of the complication (Table 5). These codes to describe severity are subjective, but help stratify the significance of the complication. Please note that the complete detailed lists of nomenclature (shown in part in Tables 1, 2, 3, 4, and 5) are all available for free download at <http://www.IPCCC.net>. These lists are also available as electronic tables from the Cardiology in the Young Website at <http://journals.cambridge.org/action/displayJournal?jid=CTY>.

Discussion

Using the structure of The International Paediatric and Congenital Cardiac Code, we have developed a comprehensive set of terms to code for the complications related to cardiac catheterisation for paediatric and congenital cardiac disease. A key feature of this set of codes is the inclusion of qualifier codes for attributability that put the complication in the context of the process of catheterisation. This feature is essential for efforts designed to improve quality.

Currently, no uniform set of terms exist to code for the complications related to cardiac catheterisation for paediatric and congenital cardiac disease. Therefore, it is impossible to compare studies from individual centres to understand what the real risk of the cardiac catheterisation is to a specific patient. This problem is best exemplified by the recent single-institution reports by Mehta and colleagues¹⁵ and Bergersen and colleagues¹⁶ that document a rate of complications of 7.3% and 19%, respectively. Standardisation of the coding of complications related to cardiac catheterisation for paediatric and congenital cardiac disease, as described in this paper, is essential for meaningful analysis of multi-institutional studies. Importantly, the nomenclature and associated codes for complications listed in this paper are identical to those within the structure of The International Paediatric and Congenital Cardiac Code where they relate to complications associated with other strategies of management, such as for surgery or arrhythmias, and are thus compatible with other existing international surgical and cardiological databases.¹

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