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Original Article

Cardiac complications associated with the treatment of patients with congenital cardiac disease: consensus definitions from the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease

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Abstract A complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome. A complication does not necessarily represent a breech in the standard of care that constitutes medical negligence or medical malpractice. An operative or procedural complication is any complication, regardless of cause, occurring (1) within 30 days after surgery or intervention in or out of the hospital, or (2) after 30 days during the same hospitalization subsequent to the operation or intervention. Operative and procedural complications include both intraoperative/intraprocedural complications and postoperative/postprocedural complications in this time interval.

The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease has set forth a comprehensive list of complications associated with the treatment of patients with congenital cardiac disease, related to cardiac, pulmonary, renal, haematological, infectious, neurological, gastrointestinal, and endocrinal systems, as well as those related to the management of anaesthesia and perfusion, and the transplantation of thoracic organs. The objective of this manuscript is to examine the definitions of operative morbidity as they relate specifically to the cardiac system. These specific definitions and terms will be used to track morbidity associated with surgical and transcatheter interventions and other forms of therapy in a common language across many separate databases.

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The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease has prepared and defined a near-exhaustive list of cardiac complications, including intraoperative complications and cardiopulmonary bypass-related complications. These cardiac complications are presented in the following subgroups:

1) Cardiac (general)
2) Cardiac – Metabolic
3) Cardiac – Residual and Recurrent cardiac lesions
4) Arrhythmia
5) Cardiopulmonary bypass and Mechanical circulatory support, and
6) Operative/Procedural.

Within each subgroup, complications are presented in alphabetical order. Clinicians caring for patients with congenital cardiac disease will be able to use this list for databases, quality improvement initiatives, reporting of complications, and comparing strategies for treatment.

Keywords: Congenital heart disease; quality improvement; patient safety; outcomes; registry; operative morbidity; paediatric; surgery; congenital abnormalities; cardiac surgical procedures; heart

Historical background

Traditionally, operative mortality has been used as the primary measure for performance, quality improvement initiatives, or comparison of strategies for treatment in congenital cardiac surgery.[1,2] However, with constant improvements in early diagnosis, characterization of risk factors and therapeutic strategies, mortality after congenital cardiac surgery has continuously decreased over the last several years.[3] Thus, systematic review and classification of organ-specific complications has become more important, but a common platform has been lacking.[4] The list of cardiac complications presented with this Supplement represents a broad consensus of the work by many individuals as well as a compilation of several lists that stems from different societies. The many Societies who have contributed to this initiative are presented in the initial Introduction manuscript of this Supplement. The guiding principle we have tried to follow is to use as much evidence-based medical data as was available. Importantly, this list includes intraoperative complications that may occur during cardiac surgery, as well as perfusion and cardiopulmonary bypass-related complications, procedure-specific complications, and unplanned reoperations or intervention following a cardiac procedure. Clinicians caring for patients with congenital cardiac disease will be able to use this list for databases, quality improvement initiatives, reporting of complications, or comparing strategies for treatment.

The Complications Short List of Complications of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons, Version 2.5, includes 13 cardiac complications out of 36 total complications. The Short List of the European Paediatric Cardiac Code contains 24 cardiac complications out of 81 total complications. Prior to this project, the Long List of the version of The International Paediatric and Congenital Cardiac Code derived form the European Paediatric Cardiac Code contained 459 periprocedural cardiac complication individual codes with 109 specific qualifiers terms. Prior to this project, the Long List of the version of The International Paediatric and Congenital Cardiac Code derived form the International Congenital Heart Surgery Nomenclature and Database Project of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons contained 123 cardiac and operative complications. The newly created comprehensive Long List of Cardiac Complications presented in this Supplement now contains 1429 complications. These Complications are all listed in Part 4 of this Supplement with their official definitions. These Complications have been incorporated into the International Paediatric and Congenital Cardiac Code for both main versions: the version derived from the European Paediatric Cardiac Code and the version derived from the International Congenital Heart Surgery Nomenclature and Database Project. Furthermore, all of these Complications in the Long List have been mapped to appropriate terms in the Short Lists of Complications in each version.

Consensus definitions

In Part 4 of this Supplement, within each organ system, complications are presented and defined

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in alphabetical order. The near-exhaustive list of cardiac complications is presented in the following subgroups:

- Cardiac (general)
- Cardiac – Metabolic
- Cardiac – Residual and Recurrent cardiac lesions
- Arrhythmia
- Cardiopulmonary bypass and Mechanical support, and
- Operative/Procedural
- Operative/Procedural-retained equipment.

In Part 4 of this Supplement, within each subgroup, complications are presented and defined in alphabetical order. The Arrhythmia subgroup is discussed in detail in another manuscript in this Supplement. Arrhythmias have been subclassified into the following subgroups:

- Arrhythmia
- Arrhythmia – Arrhythmia necessitating pacemaker
- Arrhythmia – Atrial
- Arrhythmia – Junctional
- Arrhythmia – Other
- Arrhythmia – Supraventricular tachycardia
- Arrhythmia – Ventricular
- Arrhythmia – Atrioventricular conduction disorder
- Arrhythmia – Complication of Device.

The "Cardiopulmonary bypass and Mechanical support" subgroup is also discussed in detail in another manuscript in this Supplement. Cardiopulmonary bypass and mechanical circulatory support complications have been subclassified into the following subgroups:

- Cardiopulmonary bypass
- Extracorporeal membrane oxygenation, and
- Ventricular assist devices.

Some complications that are not strictly speaking "cardiac organ related", but belong to the cardiac sphere, were also included in this Long List of Cardiac Complications. Electronic access to these items will also be possible via other hierarchical pathways within the nomenclature system, according to user preference. Such complications closely related to the cardiac system include the following examples:

- Post-operative bleeding
- Intraoperative injury to the phrenic nerve or recurrent laryngeal nerve
- Other intraoperative complications such as ligation of a wrong structure or retained intrathoracic lines, for example.

Post-operative bleeding is one of the most frequent complications after cardiac repairs. We chose to differentiate bleeding by site. The phrenic nerve or recurrent laryngeal nerves are the two nerves that are most at risk during cardiac surgery.

Controversies

Most cardiac complications have not been previously defined in the literature. Development of these definitions, therefore, often required a multispecialty expert consensus approach. We defined all complications including those with no formal literature definition. Several areas of controversies necessitated significant discussion and debate prior to eventually obtaining consensus.

Temporal relationship of a complication

We have utilized the following previously published temporal definitions of complications:[5]

> "A **complication** is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome. A complication does not necessarily represent a breech in the standard of care that constitutes medical negligence or medical malpractice. An operative or procedural complication is any complication, regardless of cause, occurring (1) within 30 days after surgery or intervention in or out of the hospital, or (2) after 30 days during the same hospitalization subsequent to the operation or intervention. Operative and procedural complications include both intraoperative/intraprocedural complications and postoperative/postprocedural complications in this time interval."

> "A **preoperative complication** is any complication that occurs or is recognized before the database field, Operating Room Entry Date and Time."

> "An **intraoperative complication** is any complication that occurs or is recognized during the time interval between the database field, Operating Room Entry Date and Time, and the database field, Operating Room Exit Date and Time."

> "A **postoperative complication** is any complication that occurs or is recognized during the time interval between Operating Room Exit Date and Time and the end of the period of operative and procedural data collection."

> "An **operative complication** is any complication that occurs during the time interval between Operating Room Entry Date and Time and the end of the period of operative and procedural data collection, and thus includes both intraoperative and postoperative complications."

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> "The **period of operative and procedural data collection** for the EACTS-STS Database includes both: (1) up to 30 days after operation if the patient has been discharged from the hospital and (2) until the EACTS-STS Congenital Database Discharge Date if a patient is still in the hospital after 30 days."

These definitions were also applied to procedural complications as well as shown below:[5]

> "A **preprocedural complication** is any complication that occurs or is recognized before the database field, Operating Room Entry Date and Time."

> "An **intraprocedural complication** is any complication that occurs or is recognized during the time interval between the database field, Operating Room Entry Date and Time, and the database field, Operating Room Exit Date and Time."

> "A **postprocedural complication** is any complication that occurs or is recognized during the time interval between Operating Room Exit Date and Time and the end of the period of operative and procedural data collection."

> "A **procedural complication** is any complication that occurs during the time interval between Operating Room Entry Date and Time and the end of the period of operative and procedural data collection, and thus includes both intraprocedural and postprocedural complications."

Another controversial area related to the timing of complications relates to the use of the words acute versus subacute versus chronic, as exemplified by the concept of acute versus subacute versus chronic failure of a Fontan operation, in other words "Fontan failure". Presently, only general guidelines exist, and we have used the 24 hour postoperative mark to establish whether a complication is acute or subacute.

> "Fontan failure is defined as failure of Fontan operation to adequately sustain perfusion and gas exchange, resulting in Fontan take-down, Fontan revision, mechanical circulatory support, or listing for cardiac transplantation."

> "Acute Fontan failure is defined as Fontan failure within 24 hours of Fontan creation."

> "Chronic Fontan failure is defined as Fontan failure after hospital discharge from Fontan creation and after 30 days after Fontan creation."

> "Subacute Fontan failure is defined as Fontan failure greater than or equal to 24 hours after Fontan creation but during same hospitalization as Fontan creation, or Fontan failure greater than or equal to 24 hrs after Fontan creation and after hospital discharge from Fontan creation but within 30 days of Fontan creation."

Additional temporal stratification is present in the list where appropriate, such as cardiac arrest prior, during or following a procedure, as exemplified by the following three terms:

- Cardiac arrest timing, Cardiac arrest before procedure (Preoperative/Preprocedural)
- Cardiac arrest timing, Cardiac arrest during procedure (Intraoperative/Intraprocedural)
- Cardiac arrest timing, Cardiac arrest following procedure (Postoperative/Postprocedural).

Complication that is specific to a given procedure

Complications that are specific to given procedures include the following examples taken directly from the list presented in Part 4 of the Supplement:

- "Cavopulmonary connection complication involving superior cavopulmonary connection, Stenosis"
- "Coronary arterial complication, Complications following repair of anomalous pulmonary origin of coronary, Complications following repair via Takeuchi operation (Intrapulmonary tunnel), Postprocedural pulmonary trunk baffle leak after intrapulmonary trunk tunnel (Takeuchi) for anomalous coronary artery."

This portion of the list will obviously remain incomplete as new procedures and new complications will undoubtedly emerge in the future.

We also tried to avoid making the list too detailed by adding every complication for every procedure; therefore, not every procedure-specific complication has been included when a generic, higher level complication will suffice and it can be qualified with a generic modifier term. Finally, many complications are procedure-related but not procedure-specific, such as post-operative bleeding and post-operative cardiac arrest, and are thus included as generic complications.

Residual and recurrent cardiac lesions

Residual and recurrent cardiac lesions are defined as follows:[6]

> "A residual lesion is a lesion that is present at the time of the completion of an operation or intervention. Residual lesions may be secondary to three etiologies: (1) Attempted therapy to treat the lesion may have failed, (2) The lesion may have been intentionally not treated and purposefully left present, and (3) Knowledge of the lesion may not have existed until completion of the operation or intervention. A recurrent lesion is a lesion that was present at the beginning of an operation or intervention and was not present at the completion of the operation or intervention but then develops at some time after the completion of the operation or intervention. In many cases, it may not

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be possible to truly know if a complication is residual or recurrent."

The following 5 terms will allow the clear documentation of the impact of a residual or recurrent cardiac lesion, and whether this lesion is residual or recurrent if that fact is known.

- Residual or recurrent cardiac lesion
- Residual or recurrent cardiac lesion, Requiring reoperation or reintervention
- Residual or recurrent cardiac lesion, Requiring reoperation or reintervention during this admission or requiring reoperation or reintervention within 30 days of the original operation or intervention
- Residual or recurrent cardiac lesion-modifier for recurrent cardiac lesion
- Residual or recurrent cardiac lesion-modifier for residual cardiac lesion.

Precise definition of certain complications

The precise definition of several terms proved to be difficult and sometimes impossible, to find in the literature. The occurrence of new symptoms related to a complication (such as superior caval vein syndrome in the setting of anastomotic narrowing after a superior bidirectional cavopulmonary anastomosis); or the need for an unplanned intervention related to that complication, are usually obvious components of the definition, and in some cases the only component of the definition (see "Fontan Failure").

Another example relates to echocardiographic or catheterization parameters. Although these are objective, more precise, and useful in themselves, leaving no room for clinician-related subjectivity, they are also much harder to define specifically with respect to a particular complication. For instance, how much residual left ventricular outflow tract gradient defines a complication; how should it be measured and what cardiac index is assumed? Whenever possible, we have used the published parameters for technical scoring currently in development in Boston.[2,7]

Devices

With the increasing use of devices both in the catheterization laboratory and in the operating room ("hybrid" techniques), we felt that it was important to include as many device-related complications as possible.

Prolonged chest tube output after the Fontan procedure

A review of the literature revealed that need for chest tube after 5 days post-operative is a reasonable median cut-off point for calling it a complication.[8]

The term "clinically significant"

We have tried to avoid this term as it implies a clinical judgment, and have endeavoured to replace it with evidence-based metrics. In some complications, however, such as pulmonary vein or systemic vein obstruction, the words "clinically significant" are needed, because no evidence-based measures exist, and the complication can present without symptoms or need for intervention.

Complications during cardiopulmonary bypass, extracorporeal life support and ventricular assist devices:

Complications during support with cardiopulmonary bypass, extracorporeal membrane oxygenation, and ventricular assist devices were grouped together. These complications of cardiopulmonary bypass and mechanical support are discussed in detail in a separate manuscript in this Supplement.

Operative/Procedural

To our knowledge, this is the first complications list to include detailed intraoperative complications.[9]

Complications related to intraoperative echocardiography

Both epicardial and transesophageal echocardiography have complications that are procedure-specific.[10,11] The risk/benefit for performing intraoperative transesophageal echocardiography remains uncertain for many lesions, and inclusion of this information in acquisitions of data related to cardiac surgery is the only meaningful way to address this issue.

Interaction with the cardiac system

Ventricular-ventricular interaction

The concept of ventricular-ventricular interaction was introduced to highlight the fact that ventricular dysfunction can occur because of ventricular interaction or interdependence. The term "right ventricular to left ventricular interaction" refers to forces transmitted from one ventricle to the other through the septum or pericardium. This interaction is always present when there are two separate ventricles and atria and influences both normal and abnormal physiology.[12] The phenomenon is of most interest when the effect exceeds the normal magnitude, with manifestations such as left ventricular dysfunction secondary to right ventricular volume overload or right ventricular dysfunction.[13] An example of a situation where this phenomenon can become important is a child with pulmonary atresia and intact ventricular septum who is ill because a dilated and hypertensive right ventricle

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leads to left ventricular dysfunction. A similar example is a child with hypoplastic left heart syndrome who is disproportionately sick because of a dilated and hypertensive left ventricle. Thus, the concept of interactions between organ systems can be extended to ventricular to ventricular interactions within the heart itself.

Conclusion

The present list represents a near-exhaustive compilation of cardiac complications occurring before, during and after congenital cardiac surgery. Intraoperative and cardiopulmonary bypass-related complications were also included. Clinicians caring for patients with congenital cardiac disease will be able to use this list for databases, quality improvement initiatives, reporting of complications, or comparing treatment strategies.

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