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Original Article

Pulmonary 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 pulmonary 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.

As surgical survival in children with congenital cardiac disease has improved in recent years, focus has necessarily shifted to reducing the morbidity of congenital cardiac malformations and their treatment. A comprehensive list of pulmonary complications is presented. This list is a component of a systems-based compendium of complications that will standardize terminology and thereby allow the study and

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quantification of morbidity in patients with congenital cardiac malformations. Clinicians caring for patients with congenital cardiac disease will be able to use this list for databases, initiatives to improve quality, reporting of complications, and comparing strategies of treatment.

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

Historical background

The fields of cardiac intensive care, cardiac surgery, cardiac anaesthesia and cardiology continue to advance exponentially. The survival of patients with critical congenital cardiac disease is seldom in question in the modern era. During the past two decades, mortality after surgery for congenital cardiac disease has decreased dramatically and is now 4% in several large multicentric studies.[1,2] Consequently, the focus of clinical research and efforts to improve quality has now shifted to that of the minimization of morbidity.

Both mortality[3] and morbidity[4] have been defined for a cardiac surgical registry database. Complications and death may, however, occur in the congenital cardiac population in the absence of surgical treatment. Additionally, a systematic review and classification of organ-specific complications delineated in a common platform has not been published. These issues prompted The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease to undertake the task of defining organ-specific complications in relation to congenital cardiac disease. Importantly, this compilation of complications can be applied to surgical and non-surgical patients alike, regardless of manner or stage of therapy.

An extensive search through Medline and multiple textbooks was performed to identify the existing literature that provides definitions of the identified pulmonary complications. All participants on the subcommittee of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease responsible for pulmonary complications reviewed the available data and contributed to the consensus definitions. Members of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease participated in refining all definitions offered in this article by telephone conferences, e-mail correspondence, and multiple face to face meetings. All participating members reviewed and approved the final definitions in this report.

Consensus definitions

The terms in the final list of pulmonary complications developed by The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease, along with their official definitions are listed in Part 4 of this Supplement.

Controversies

Most pulmonary complications have been defined in the literature previously and were agreed upon without much discussion. A "gradation" of complications was purposefully avoided as we chose merely to document their presence or absence, and whether or not intervention was performed. There were three complications that engendered a fair amount of debate:

- Respiratory arrest
- Duration of mechanical ventilation
- Ventilator-associated pneumonia.

The definitions of morbidity and mortality following cardiac surgery were purposefully crafted to associate those outcomes with a primary procedure. For example, a urinary tract infection on post-operative day fourteen is linked to that operation because it is assumed that if the patient did not have the operation then there would have been no foley catheter and thus no urinary tact infection. This strategy, while all-encompassing, does not account for underlying conditions, such as vesicoureteral reflux, which are independent of the patient's cardiac status and may predispose to complications. Thus, for the purpose of identifying pulmonary complications, we agreed that respiratory arrest would be divided into two types – primary and secondary. This separation allows for the differentiation of primary respiratory arrest from respiratory arrest caused by circulatory insufficiency from other causes, in other words, secondary respiratory arrest. The following definition is proposed for respiratory arrest:

> "Respiratory arrest is defined as the loss of spontaneous respiration requiring unanticipated airway support. Respiratory arrest during the period of anesthetic care can be coded more specifically under Anesthesia. Respiratory arrest during transportation can be coded more specifically under Anesthesia – Transport. Primary respiratory arrest is when airway obstruction, decreased respiratory drive, or respiratory muscle weakness results in hemodynamic instability (bradycardia, hypotension) or collapse.

Secondary respiratory arrest is when preceding circulatory insufficiency results in cessation of respiratory activity."

Respiratory arrest therefore may be further subclassified:

- Respiratory arrest, Not known if primary respiratory arrest or secondary respiratory arrest
- Respiratory arrest, Primary respiratory arrest
- Respiratory arrest, Secondary respiratory arrest.

In discussions regarding duration of mechanical ventilation, it was difficult to agree on a practical method of tracking the number of hours or days on mechanical ventilation, especially in patients with long post-operative courses and multiple episodes of intubation and extubation. As a group we chose to use the guidelines of The Society of Thoracic Surgeons Congenital Database because these guidelines yield an easily determinable time.[4,5] These guidelines have been published in The Annals of Thoracic Surgery:[4]

Intubation Date and Time
The date and time, using a 24-hour clock, that ventilatory support started. Specific guidelines are offered in version 2.50 of the "Database Specifications of The Society of Thoracic Surgeons" that address issues such as tracheostomy in place at admission, patient intubated at admission, unintended extubations, elective tube changes, and unknown intubation date and time, among others.

Initial Extubation Date and Time
The date and time, using a 24-hour clock, that ventilatory support initially ceased after surgery. Specific guidelines are offered in version 2.50 of the "Database Specifications of The Society of Thoracic Surgeons" that address issues surrounding extubation time for the patient with a tracheostomy, the patient who expires while intubated, and the patient discharged on chronic ventilatory support, among others.

Final Extubation Date and Time
The date and time, using a 24-hour clock, that ventilatory support last ceased prior to discharge after surgery. Specific guidelines are offered in version 2.50 of the "Database Specifications of The Society of Thoracic Surgeons" that address issues surrounding final extubation time for the patient with a tracheostomy, the patient who expires while intubated, and the patient discharged on chronic ventilatory support, among others.

Postoperative Length of Time Until Initial Extubation
The interval between the time the operation ended, as indicated by the "Operating Room Exit Date and Time", and the "Initial Extubation Date and Time".

Postoperative Length of Time Until Final Extubation
The interval between the time the operation ended, as indicated by the "Operating Room Exit Date and Time" and the "Final Extubation Date and Time".

These guidelines have been published in more detail on the website of The Society of Thoracic Surgeons[5]:

Intubation Date and Time
The Intubation Date and Time is defined as the date (mm/dd/yyyy) and time (hh:mm) (24 hour clock) ventilatory support started. The following guidelines are offered in version 2.50 of the "Database Specifications of The Society of Thoracic Surgeons"

1. Indicate the date (mm/dd/yyyy) and time (hh:mm) (24 hour clock) ventilatory support started.
2. Capture the intubation closest to the surgical start time.
3. If the patient was intubated upon admission and remained intubated until the surgical start time, capture this intubations date and time. (In other words, if the patient was intubated upon admission to the hospital and remained intubated until the surgical start time, capture the date and time of this "intubation upon admission to the hospital").
4. If the patient was admitted intubated (intubated at another institution) and remained continually intubated until the surgical start time, capture the patient's admission date and time.
5. If the patient was admitted with a tracheostomy in place without ventilatory support, capture the date and time closest to the surgical start time that ventilatory support was initiated.
6. If the patient was admitted with a tracheostomy in place receiving chronic ventilatory support, capture the admission date and time.
7. If the intubation date and time is otherwise unknown, enter the date and time the patient entered the operating room.
8. Do not alter the previously established date and time that ventilatory support was initiated for scenarios including, but not limited to, interruptions in ventilatory support due to accidental extubation/de-cannulation, elective tube change etc.

Initial Extubation Date and Time
The Initial Extubation Date and Time is defined as the date (mm/dd/yyyy) and time (hh:mm) (24 hour clock) ventilatory support initially ceased after surgery. The following guidelines are offered in version 2.50 of the "Database Specifications of The Society of Thoracic Surgeons":

1. Indicate the date (mm/dd/yyyy) and time (hh:mm) (24 hour clock) ventilatory support initially ceased after surgery.

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2. Capture the extubation closest to the surgical stop time.
3. If the patient has a tracheostomy and is separated from the mechanical ventilator postoperatively within the hospital admission, capture the date and time of separation from the mechanical ventilator closest to the surgical stop time.
4. If the patient expires while intubated or/cannulated and on the ventilator, capture the date and time of expiration.
5. If patient discharged on chronic ventilatory support, capture the date and time of discharge.

Final Extubation Date and Time

The Final Extubation Date and Time is defined as the date (mm/dd/yyyy) and time (hh:mm) (24 hour clock) ventilatory support last ceased prior to discharge after surgery. The following guidelines are offered in version 2.50 of the "Database Specifications of The Society of Thoracic Surgeons":

1. Indicate the date (mm/dd/yyyy) and time (hh:mm) (24 hour clock) ventilatory support initially ceased after surgery.
2. Capture the extubation time closest to EACTS-STS Congenital Database Discharge Date.
3. If the patient has a tracheostomy and is separated from the mechanical ventilator more than once postoperatively within the hospital admission, capture the date and time of separation from the mechanical ventilator closest to the EACTS-STS Congenital Database Discharge Date.
4. If the patient expires while intubated or cannulated and on the ventilator, capture the date and time of expiration.
5. If the patient was discharged on chronic ventilatory support, capture the date and time of the EACTS-STS Congenital Database Discharge.

Postoperative length of time until initial extubation

The postoperative length of time until initial extubation is the time interval between the time the operation ended (as indicated by the OR Exit Date and Time) and the Initial Extubation Date and Time.

Postoperative length of time until final extubation

The postoperative length of time until final extubation is the time interval between the time the operation ended (as indicated by the OR Exit Date and Time) and the Final Extubation Date and Time.

These intervals of time are being used with other variables within the database as an *overall* marker of morbidity, in other words, as a surrogate for morbidity. This concept is discussed in greater detail elsewhere in this Supplement in the article by Lacour-Gayet and colleagues titled "The Morbidity Index". In short, these time intervals are being used as a component of an index to quantify generalized morbidity. In this context, these time intervals are not being used to quantitate morbidity specific to the pulmonary system. The value of these time intervals as markers of morbidity is currently being assessed. As we strive to identify and track complications specific to organ-systems, these definitions will need to be interpreted in a fashion such that procedures for other morbidities, such as gastrostomy tube for feeding intolerance requiring intubation for placement, do not falsely elevate markers of pulmonary morbidity.

No "gold-standard" definition exists for the diagnosis of "ventilator-associated pneumonia", commonly referred to as "VAP". The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease proposes the following definitions for pneumonia and "ventilator-associated pneumonia":

> "Pneumonia is defined as a "respiratory disease characterized by inflammation of the lung parenchyma (including alveolar spaces and interstitial tissue), most commonly caused by infection". Pneumonia is diagnosed by appropriate clinical findings (such as fever, leukopenia or leukocytosis, and new onset of purulent sputum) and one or more of the following: positive cultures (of sputum or pulmonary secretions) and/or pulmonary infiltrate on chest X-ray. An endotracheal tube culture may or may not be positive. Patients commonly demonstrate an evolving area of focal lung consolidation accompanied by fever (>38.5). Pneumonia (pneumonitis) may affect an entire lobe (lobar pneumonia), a segment of a lobe (segmental or lobular pneumonia), alveoli contiguous to bronchi (bronchopneumonia), or interstitial tissue (interstitial pneumonia). These distinctions are generally based on X-ray observations."

> "Ventilator-associated pneumonia (VAP) is defined as a new onset pneumonia that develops in patients who have been on mechanical ventilation for greater than 48 hours."

Ventilator-associated pneumonia develops in approximately one-fifth of critically ill adult patients receiving mechanical ventilation. Patients in whom ventilator-associated pneumonias develop have a higher rate of mortality, longer stays in intensive care units, and require more resources, than those without the disease.[6] Ventilator-associated pneumonia is most accurately diagnosed by quantitative culture and microscopic examination of lower respiratory tract secretions, which can be obtained by bronchoscopically directed techniques such as the protected specimen brush and quantitative culture of

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Table 1. Definition of pneumonia provided by the Center for Disease Control and Prevention of the United States of America.

Two or more serial chest radiographs with at least *one* of the following:[1,2]

1. New or progressive *and* persistent infiltrate
2. Consolidation
3. Cavitation
4. Pneumatoceles, in infants ≤1 year old

NOTE: In patients without underlying pulmonary or cardiac disease (e.g., respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), *one definitive* chest radiograph is acceptable[1].

PLUS

FOR ANY PATIENT, at least *one* of the following:

- Fever (>38°C or >100.4°F) with no other recognized cause
- Leukopenia (<4,000 WBC/mm^3) *or* leukocytosis (≥12,000 WBC/mm^3)
- For adults ≥70 years old, altered mental status with no other recognized cause

And, at least *two* of the following:

- New onset of purulent sputum,[3] or change in character of sputum,[4] or increased respiratory secretions, or increased suctioning requirements
- New onset or worsening cough, or dyspnea, or tachypnea[5]
- Rales[6] or bronchial breath sounds
- Worsening gas exchange (e.g., O_2 desaturations [e.g., PaO_2/FiO_2 ≤240],[7] increased oxygen requirements, or increased ventilation demand).

ALTERNATE CRITERIA FOR INFANT ≤1 YEAR OLD:

Worsening gas exchange (e.g., O_2 desaturations, increased oxygen requirements, or increased ventilator demand)
And, at least *three* of the following:

- Temperature instability with no other recognized cause
- Leukopenia (<4,000 WBC/mm^3) *or* leukocytosis (≥15,000 WBC/mm^3) and left shift (≥10% band forms)
- New onset of purulent sputum,[3] or change in character of sputum,[4] or increased respiratory secretions, or increased suctioning requirements
- Apnea, tachypnea,[5] nasal flaring with retraction of chest wall, or grunting
- Wheezing, rales,[6] or rhonchi
- Cough
- Bradycardia (<100 beats/min) or tachycardia (>170 beats/min).

ALTERNATE CRITERIA FOR CHILD >1 OR ≤12 YEARS OLD, at least *three* of the following:

- Fever (>38.4°C or >101.1°F) or hypothermia (<37°C or <97.7°F) with no other recognized cause
- Leukopenia (<4,000 WBC/mm^3) *or* leukocytosis (≥15,000 WBC/mm^3)
- New onset of purulent sputum,[3] or change in character of sputum,[4] or increased respiratory secretions, or increased suctioning requirements
- New onset or worsening cough or dyspnea, apnea, or tachypnea[5]
- Rales[6] or bronchial breath sounds
- Worsening gas exchange (e.g., O_2 desaturations [e.g., pulse oximetry <94%], increased oxygen requirements, or increased ventilation demand).

1. Occasionally, in nonventilated patients, the diagnosis of nosocomial pneumonia may be quite clear on the basis of symptoms, signs, and a single definitive chest radiograph. However, in patients with pulmonary or cardiac disease (e.g., interstitial lung disease or congestive heart failure), the diagnosis of pneumonia may be particularly difficult. Other noninfectious conditions (e.g., pulmonary edema from decompensated congestive heart failure) may simulate the presentation of pneumonia. In these more difficult cases, serial chest radiographs must be examined to help separate infectious from noninfectious pulmonary processes. To help confirm difficult cases, it may be useful to review radiographs on the day of diagnosis, 3 days prior to the diagnosis, and on days 2 and 7 after the diagnosis. Pneumonia may have rapid onset and progression but does not resolve quickly. Radiographic changes of pneumonia persist for several weeks. As a result, rapid radiograph resolution suggests that the patient does *not* have pneumonia but rather a noninfectious process such as atelectasis or congestive heart failure.
2. Note that there are many ways of describing the radiographic appearance of pneumonia. Examples include, but are not limited to, air-space disease, focal opacification, and patchy areas of increased density. Although perhaps not specifically delineated as pneumonia by the radiologist, in the appropriate clinical setting these alternative descriptive wordings should be seriously considered as potentially positive findings.
3. Purulent sputum is defined as secretions from the lungs, bronchi, or trachea that contain ≥25 neutrophils and ≤10 squamous epithelial cells per low power field (X100). If your laboratory reports these data qualitatively (e.g., many WBCs or few squames), be sure their descriptors match this definition of purulent sputum. This laboratory confirmation is required because written clinical descriptions of purulence are highly variable.
4. A single notation of either purulent sputum or change in character of the sputum is not meaningful; repeated notations over a 24-hour period would be more indicative of the onset of an infectious process. Change in character of sputum refers to the color, consistency, odor, and quantity.
5. In adults, tachypnea is defined as respiration rate >25 breaths per minute. Tachypnea is defined as >75 breaths per minute in premature infants born at <37 weeks' gestation and until the 40th week; >60 breaths per minute in patients <2 months old; >50 breaths per minute in patients 2–12 months old; and >30 breaths per minute in children >1 year old.
6. Rales may be described as crackles.
7. This measure of arterial oxygenation is defined as the ratio of the arterial tension (PaO_2) to the inspiratory fraction of oxygen (FiO_2).

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the bronchoalveolar-lavage fluid or endotracheal aspiration with nonquantitative culture of the aspirate.[7] Some of these techniques are not readily or easily performed in neonates and children. Care must be taken when assessing intubated patients to distinguish between tracheal colonization, upper respiratory tract infections, such as tracheobronchitis, and early onset pneumonia. Finally, it should be recognized that it may be difficult to determine nosocomial pneumonia in the elderly, infants, and immunocompromised patients, because such conditions may mask typical signs or symptoms associated with pneumonia. We have chosen to adopt the definitions of pneumonia provided by the Center for Disease Control and Prevention of the United States of America, with special attention to the criteria in the above mentioned special populations of patients (Table 1). We are cognizant of the difficulties in diagnosing ventilator-associated pneumonia in the pediatric population and realize that our capture of this entity may be incomplete.[8]

Interaction with the cardiac system

Dynamic and structural properties of the heart and lungs, and their close anatomical and functional relation, play an important role in determining the haemodynamic influences of mechanical ventilation and pulmonary complications. Ventilation can profoundly alter cardiovascular function via complex, conflicting, and often opposite processes. These processes reflect the interaction between many factors:

- ventricular function
- the circulating volume blood
- the distribution of the flow of blood
- autonomic tone
- the volume of air in the lungs, or pulmonary volume, and
- intrathoracic pressure.[9]

First, spontaneous ventilation is exercise, and critically ill patients may not withstand the increased work of breathing. Initiation of mechanical ventilatory support will improve the delivery of oxygen by decreasing work of breathing and thus redistributing the flow of blood to other organs. In patients with functionally univentricular physiology, to the extent that mixed venous oxygen also increases, arterial oxygen content will increase without any improvement in gas exchange.

Second, changes in pulmonary volume alter autonomic tone and pulmonary vascular resistance, and at high pulmonary volumes compress the heart. Hyperinflation increases pulmonary vascular resistance and the pressure in the pulmonary arteries, impeding right ventricular ejection. Decreases in pulmonary volume induce alveolar collapse and hypoxia, stimulating an increased pulmonary vasomotor tone by the process of hypoxic pulmonary vasoconstriction. Manoeuvres of alveolar recruitment, positive end-expiratory pressure, and continuous positive airway pressure may reverse hypoxic pulmonary vasoconstriction and reduce the pressure in the pulmonary arteries. In patients with single ventricle physiology, pulmonary venous desaturation has been shown to confound the assessment of the ratio of pulmonary to systemic blood flow, commonly referred to as "Qp:Qs", and impair oxygen delivery.[10]

Third, spontaneous inspiration and inspiratory efforts decrease intrathoracic pressure and increase intra-abdominal pressure. These combined effects cause right atrial pressure to decrease but venous pressure in the abdomen to increase, markedly increasing the gradient of pressure for systemic venous return. Furthermore, the greater the decrease in intrathoracic pressure, the greater the increase in left ventricular afterload for a constant arterial pressure. Mechanical ventilation, by abolishing the negative swings in intrathoracic pressure, will selectively decrease left ventricular afterload, as long as the increases in pulmonary volume and intrathoracic pressure are small. In patients with cardiac failure and overload of volume, this reduction in afterload can result in improved left ventricular ejection, increased cardiac output, and reduced myocardial demand of oxygen. Positive-pressure ventilation, however, increases intrathoracic pressure, such that in hypovolemic states, it can induce profound decreases in venous return. Additionally, patients with univentricular physiology, where the flow of pulmonary blood is passive, will benefit from negative-intrathoracic pressure, in other words, spontaneous ventilation.[11] Most cardiac centres adopt an aggressive early extubation strategy in these patients to avoid the negative impact of mechanical ventilation. Patients receiving mechanical ventilation also can develop auto-positive end-expiratory pressure. "Auto-positive end-expiratory pressure", often referred to as "autoPEEP" is gas trapped in alveoli at end expiration, due to inadequate time for expiration, bronchoconstriction or plugging of mucus. It can increase the work of breathing, worsen the exchange of gas, and decrease cardiac output. The relationship between ventilatory pressures and cardiac output must be continuously assessed and balanced.[12–16] Clearly, the final response to ventilatory stress is dependent on the baseline cardiovascular state of the subject, including the myocardial function of the patient and the state of the circulatory volume of the patient.

Likewise cardiac compromise can have profound effects on pulmonary performance. In patients with

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diastolic dysfunction, elevated left ventricular end-diastolic pressure will elevate pulmonary venous pressure, resulting in elevated pulmonary vascular resistance, pulmonary oedema and impaired oxygenation. An appreciation of these problems is essential for optimal intensive care management. Indeed, it is essential to consider the heart and lungs as an integral cardiopulmonary unit rather than as two separate systems. This strategy will help to minimize complications and morbidity.

Conclusion

The present list represents a comprehensive compilation of pulmonary complications associated with the treatment of patients with congenital cardiac disease. These complications can occur before, during and after cardiac surgery and intervention. Clinicians caring for patients with congenital cardiac disease will be able to use this list for databases, initiatives to improve quality, reporting of complications, and comparing strategies of treatment.

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