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Cardiac Arrest Associated with Endotracheal Suctioning Following Surgery for Congenital Heart Disease

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Acknowledgements

In 2010, Dr. Patricia Hickey presented to the nursing staff the Institute of Medicine Report: *The Future of Nursing: Leading Change, Advancing Health*. This was a sentinel moment for me; I began considering how I could use the expertise I had gained over the years to influence the care of my patients. Then in 2011, Dr. Jean Connor and Dr. Sandra Mott, with the support of Dr. Hickey, established the *Nursing Science Fellowship*. I had worked with Dr. Connor briefly months before on a QI project and she saw something in me that I had not yet seen in myself, which gave me the belief I could apply to this program. I then had the privilege of the two-year nursing fellowship experience, asking and answering my own research questions while being mentored by Drs. Connor and Mott. Learning from these amazing mentors was a pivotal experience. After 25 years as a nurse, I was ready to return to school, now knowing I could do it!

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Abstract

Congenital heart disease (CHD) describes the most common congenital defect and represents a significant health burden worldwide. Yearly, there are more than a million newborns diagnosed with congenital heart disease; many of the defects require surgical correction. The cost of surgical correction can be significant; of the ten congenital defects with the highest hospital cost, six are CHD. Cardiac arrest, like other postoperative complications, can increase the length of intensive care and hospital stay, and is associated with hospital-acquired infections, errors, and poorer long-term outcomes. Several studies included physiological data and hemodynamic monitoring or assigned causation for cardiac arrest to broad categories, such as respiratory, arrhythmia, metabolic or central nervous system, but did not describe specific clinical signs of impending cardiac arrest with the exception of rising serum lactate. The paucity of data in this area demonstrates a gap in the literature on cardiac arrest in children following cardiac surgery.

The first manuscript in this dissertation describes the current literature on the effect of endotracheal suctioning in pediatrics, guided by the Neuman Systems model. The second manuscript, using the Knowledge-to-Action theoretical framework, explores available tools for risk adjustment in congenital heart surgery. Lastly, the third manuscript describes the hemodynamic variability preceding cardiac arrest associated with endotracheal suctioning in children following surgery for congenital heart defects compared to others. This dissertation establishes a basis for further research and interventions to avert cardiac arrest in the vulnerable child with congenital heart disease.

Key words: congenital heart disease, suctioning, cardiac arrest, risk adjustment, pediatrics

Introduction

CHD represent 28% of all congenital defects (Mitchell, Korones, & Berendes, 1971; Van der Linde et al., 2011). Worldwide prevalence has been cited as 8 per 1,000 births, but the most recent research by Van der Linde et al. (2011) indicates an increase over time to 9.1 per 1,000 live births since 1990. In terms of global distribution, the highest prevalence is reported in Asia at 9.3 per 1,000 births and the lowest in Africa at 1.9 per 1,000 births (Bernier, Stefanescu, Samoukovic, & Tchervenkov, 2010). A relationship exists between prevalence and a country's average income, with the highest rates in countries with the highest incomes, thereby suggesting global health disparities. Countries with a lower standard of living generally have limited resources in terms of both access and procedures for screening and referral, which may lead to underreporting and more importantly, a barrier to appropriate care (Ferencz et al., 1985).

Each year 1.35 million newborns are diagnosed with CHD; many of these defects require surgical correction (Van der Linde et al., 2011). The cost of surgical correction can be significant. The Centers for Disease Control and Prevention (2007) reported that, of the ten congenital defects resulting in the highest hospital cost, six were CHD. The highest costing defects were hypoplastic left heart syndrome and truncus arteriosis, both of which require surgical intervention as a neonate or young infant. In a study on the variation in cost among types of congenital heart surgery, Pasquali, Gaies, Jacobs, Gaynor, and Jacobs (2012) found that, among 27 hospitals with 12,718 surgeries of various complexity, cost ranged from $25,499 to $165,168 per hospitalization. As expected, the cost increased as length of stay increased; complications additionally increased costs.

Congenital heart defects present in one of three general categories based on degree of pulmonary blood flow. Defects with increased pulmonary blood flow include atrial septal defects, ventricular septal defects, and patent ductus arteriosus (Ofori-Amanfo & Cheifetz, 2013). These patients are acyanotic and have symptoms of congestive heart failure. Defects with decreased pulmonary blood flow may include tetralogy of Fallot, pulmonary stenosis, or pulmonary atresia (Ofori-Amanfo & Cheifetz, 2013). These children may or may not be cyanotic, contingent on the degree of obstruction of blood flow to the lungs. Intervention may be required shortly after birth or may be amenable to delay until an older age. A more critical variation of decreased pulmonary blood flow is transposition of the great arteries (TGA). In this defect, pulmonary and systemic blood flow is parallel rather than in series (Ofori-Amanfo & Cheifetz, 2013). Desaturated venous blood is returned to the body via the malpositioned aorta, and oxygenated pulmonary blood is returned back to the lungs unable to exit to the body. This defect requires immediate intervention following birth. The third category of heart defects has obstruction to systemic blood flow. Defects include hypoplastic left heart syndrome, critical coarctation of the aorta and critical aortic valve stenosis (Ofori-Amanfo & Cheifetz, 2013). These children require intervention shortly after birth and can develop circulatory shock without timely treatment (Ofori-Amanfo & Cheifetz, 2013). Medical and nursing expertise is vital to recognize and intervene as appropriate for the defect and the clinical condition (Ofori-Amanfo & Cheifetz, 2013; Peddy et al., 2007).

Critically ill children often require invasive ventilatory support during the course of their treatment. Short-term invasive ventilatory support is achieved by tracheal intubation with an endotracheal tube. Individuals with an endotracheal tube require suctioning to maintain the patency of the artificial airway. The process of suctioning requires an interruption in mechanical ventilation and introduction of negative pressure into the airways through the application of suction. This process may result in unexpected adverse effects, such as pulmonary hypertension, hypoxia, bradycardia, blood pressure instability, and cardiac arrest. These adverse effects of endotracheal suctioning can be particularly detrimental to cardiopulmonary interaction in children with CHD, an increased vulnerability during this routine procedure.

Failure to rescue is defined as an complication related to the primary illness or a complication of medical care that occurs when signs and symptoms of the impending event are unrecognized, are recognized too late to avert the event, or caregivers fail to take appropriate precautions (National Quality Forum, 2015). These complications can include cardiac arrest, shock, or hospital acquired infections or injuries. The National Quality Forum considers the incidence of these complications as a performance measure of quality care (Pasquali, M. Gaies, et al., 2012). In children with CHD, it is not sufficient to presume that cardiac arrest is not preventable owing the severity of illness; clinicians must continuously seek to uncover the indicators that can alert caregivers in time to avert arrest thus avoiding a "failure to rescue". Children with cardiac diseases, hospitalized for any reason, had a significantly higher risk (7 per 1,000 hospitalizations) of cardiac arrest than those without cardiac disease (0.54 per 1,000 hospitalizations) in a dataset of nearly 500,000 inpatient admissions from three data collection years (Lowry et al., 2013). Numerous studies have shown that high performing centers, those with low mortality, have lower "failure to rescue" rates and therefore, an associated low mortality rate (Pasquali, M. Gaies, et al., 2012; Pasquali, He, et al., 2012; S. K. Pasquali et al., 2012;

Silber, Williams, Krakauer, & Schwartz, 1992). Yet even in high performing centers, the complication of cardiac arrest in the highest risk group was still shown to be 53% (Pasquali, He, et al., 2012). Furthermore, Rossano, Naim, Nadkarni, and Berg (2014) reported that cardiac arrest in specialized intensive care units, such as a pediatric cardiac intensive care unit, might be as high as 4% of admissions. In a cardiac intensive care unit with 1,000 admissions per year, 4% equates to 40 cardiopulmonary resuscitation (CPR) events annually for a single center (Peddy et al., 2007). Mortality rates are lower and neurological outcomes better for inpatient cardiac arrests as compared to out-of-hospital cardiac arrests; yet, it would be more beneficial to the patient to commit resources to prevent cardiac arrest rather than improving resuscitation skills (Parra et al., 2000). Endotracheal suctioning is a routine procedure in pediatric cardiovascular intensive care units but is not without risk; therefore, it is crucial to research dynamics contributing to cardiovascular arrest, especially modifiable factors that, if changed, can prevent or forestall cardiovascular arrest, and subsequently facilitate changes in practice and improve outcomes.

Specific Aims

This dissertation answers the question, are there hemodynamic markers that may indicate susceptibility to cardiac arrest during the routine task of endotracheal suctioning following surgery for congenital heart disease? Three manuscripts make up this dissertation: (1) an integrative review of the effects of endotracheal suctioning in the pediatric population; (2) an integrative review of the instruments for risk adjustment in CHD; and (3) a retrospective study of the hemodynamic variability preceding cardiac arrest associated with endotracheal suctioning in children following surgery for CHD.

Cardiac arrest is a known risk during endotracheal tube suctioning, particularly in those with CHD. This dissertation presents an examination of endotracheal suctioning in pediatrics, tools for risk stratification in congenital heart disease, and culminates in the investigation of children with congenital heart disease that experience cardiac arrest during endotracheal suctioning, a necessary but risk-increasing component of routine care, to identify markers that indicate an increased risk of cardiac arrest.

Aim 1. How have other studies reported the effects of endotracheal suctioning in pediatric patients, and what populations of children have been included in the study samples in this area?

The first manuscript is an integrative review of the effects of endotracheal suctioning in the pediatric population. Fourteen manuscripts were included in the final review, revealing that, despite a seemingly widespread acknowledgement of the adverse effects of suctioning, literature on the topic is limited. Research focused on three areas affected by endotracheal suctioning: the neurovascular system, the respiratory system, and pain. A key finding of the review was that the majority of the studies (67%) examining the effects of endotracheal suctioning were conducted in the premature infant population, with the most frequent area of attention being the pain associated with suctioning. The studies with pain as the theme used suctioning as a proxy to test interventions to decrease pain as well as methods to assess pain. Moreover, physiologic data were used as measurement variables in nearly all of the studies included in the integrative review, but the sequalae of the physiologic changes were not examined. Additionally, most of the studies excluded children with congenital cardiac, pulmonary, genetic syndromes, or neurological injury. These findings suggest a gap in the literature regarding the physiologic effects of endotracheal suctioning in pediatrics, particularly in the complex and vulnerable population of children with CHD.

Aim 2. What are the existing instruments for risk adjustment in congenital heart disease?

Surgery for CHD, compared to adult cardiac surgery, has significant heterogeneity, creating challenges to generating sufficient data in any single institution to assess quality of care. There are over 100 operative types, in addition to limitless innovations within these types. Measurement for risk adjustment is an important tool to compare and aggregate data across institutions. This integrative review identified the existing measurement tools for risk adjustment in congenital heart surgery. Twenty-five manuscripts applying five risk adjustment tools were included in the integrative review. The tools included the Aristotle (basic and comprehensive) score, Risk Adjustment for Congenital Heart Surgery (RACHS-1), The Society of Thoracic Surgeons-European Association of Cardio-Thoracic Surgery Congenital Heart Surgery Mortality Categories (STAT Mortality Categories), Vasoactive-inotropic score (VIS), and technical performance score (TPS). The tools varied in area of emphasis along the care continuum: complexity of surgical procedure (RACHS-1, ABC, and STAT), postoperative physiologic makers (VIS), or success of surgical technical performance (TPS). The choice of tool by a clinician or researcher was contingent on area of interest as well as the feasibility of available data and resource limitations.

Aim 3. Determine the characteristics of pediatric patients with congenital heart surgery who experienced cardiac arrest during endotracheal suctioning (Group 1), compared to those whose cardiac arrest did not occur during suctioning (Group 2), and those who experienced suctioning but not cardiac arrest (Group 3). In an exploratory analysis, identify the hemodynamic changes in physiologic parameters in intubated pediatric CHD patients 30 minutes prior to cardiac arrest. In an exploratory analysis, examine the events preceding cardiac arrest to determine any precipitating or exacerbating factors (e.g., procedures, patient care interventions, or pain/agitation).

By achieving this third aim, we identified risk factors for cardiac arrest during endotracheal suctioning, encompassing patient demographic characteristics, surgical considerations and patterns of variability in physiologic parameters preceding an arrest in children following surgery for CHD. This contribution is significant because clinicians currently rely on clinical training, experiential learning, or institutional guidelines to determine patients at risk for cardiac arrest during endotracheal suctioning. Literature on cardiac arrest in children with CHD is primarily concentrated on incidence, resuscitation procedures, and patient outcomes. In previous studies, data analyses generally started at the time of arrest and examined the interventions and outcomes that followed. In contrast, this study examined data prior to arrest to identify predictive factors.

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The Effects of Endotracheal Suctioning in the Pediatric Population: An Integrative Review

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Abstract

Background: Critically ill pediatric patients with endotracheal tubes routinely receive endotracheal tube suctioning to clear secretions and assure tube patency. This common practice can result in adverse effects.

Objectives: This integrative review presents the literature that examined the effects of endotracheal tube suctioning on the pediatric patient.

Methods: A literature review was conducted using the Whittemore and Knafl modified framework for integrative reviews. Data evaluation and analysis was performed using the Neuman System model as a theoretical framework. Databases were searched to identify published papers that met the inclusion criteria. A search of the literature was conducted via PubMed, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Scopus.

Results: This review is based on 14 papers, with a total of 849 patients, ranging in age from premature neonates to 17 years of age. The literature aligned into three groupings; neurovascular effects, respiratory systems effects and pain related to endotracheal tube suctioning. A majority (67%) of the studies were conducted in the premature neonate population. Pain was the most prevalent grouping but half used the pain of endotracheal suctioning to validate pain assessment tools. Children with congenital cardiac or pulmonary defects, genetic syndromes or neurological injuries were frequently excluded.

Conclusions: Literature regarding the physiologic effects of endotracheal suctioning is limited. Research is needed to examine the cardiopulmonary alterations that occur in response to interruptions in mechanical ventilation, introduction of airway

suction, and the ensuing pain associated with endotracheal suctioning. In addition, research is needed in older infants, toddler, school age, and adolescent pediatric patients.

The Effects of Endotracheal Suctioning in the Pediatric Population: An Integrative Review

Pediatric intensive care units (PICU) support the complex medical needs of children facing life-threatening illnesses. Critically ill children often require invasive ventilatory support during the course of their treatments. Invasive ventilatory support is most often achieved by temporary tracheal intubation with an endotracheal tube. Breathing is either partially or completely supported with a mechanical ventilator. Several factors make children more likely to require respiratory support; these include a more compliant trachea, bronchi, and rib cage; dependence on a functional diaphragm; and increased metabolic demands of the respiratory muscles.[15,16] During endotracheal intubation, the glottis is stented open, which impedes the ability to effectively move secretions. A cough is generated when an individual exhales against the closed glottis, followed by sudden opening, causing expectoration of secretions or foreign material.[17] In addition, artificial humidification is necessary and can affect mucous viscosity as well as potentially increase mucous production due to the irritation caused by the endotracheal tube or the underlying illness.[18] Consequently, each child with an endotracheal tube requires suctioning to maintain the patency of the artificial airway. The process of suctioning requires an interruption in mechanical ventilation and introduction of negative pressure into the airways through the application of suction. This process may result in unexpected adverse effects. These can include exacerbation of pulmonary hypertension, hypoxia, bradycardia or cardiac arrhythmias, vagal nerve stimulation, blood pressure changes, and changes in lung mechanics.[18] Additionally, children have additional factors that make the development of practice guidelines to avert adverse effects difficult.

Critically ill children have substantial heterogeneity. The pediatric population can range from preterm neonates through infancy, toddler, school age and teen years. Furthermore, diagnoses can include issues related to prematurity; chronic respiratory diseases such as asthma, or cystic fibrosis; congenital heart disease; pneumonia; infection; and trauma. This integrative review is guided by the following research question: How have other studies reported the effects of endotracheal suctioning in the pediatric patient, and what populations of children have been included in the study samples in this area?

Theoretical Framework

The Neuman Systems Model focuses on the wellness of the patient as he or she experiences environmental stressors and responds to these stressors.[19] Several disciplines and scholars influence Neuman's model. Her theory development encompasses de Chardin's philosophical beliefs on the wholeness of life, Marxist views regarding the oneness of man and nature, Gestalt and field theories on man/environment interactions, Bertalanffy's general systems theory on living open systems, the conceptualization of stress by Selye, and the depiction of levels of prevention by Caplan.[19] The purpose of Neuman Systems Model is to consider the environmental interactions that can affect the patient. This allows the clinician to apply preventative strategies and evaluate for causative factors.

The Neuman Systems Model visualizes a client as having continuum of energy balancing between wellness and illness.[19] The model contains five client variables: physiological, psychological, sociocultural, developmental, and spiritual.[19] The environment components consist of the internal environment, that which occurs within the client; the external environment, that which occurs outside of the client; and the created environment. The created environment is unconsciously developed by the client and employs both internal and external environment components with the purpose of providing "protective, perceptive coping" in response to stressor.[20] Stressors are the disrupting forces that can push a client away from wellness. Intrapersonal stressors occur within the client; interpersonal stressors occur at close proximity; and extrapersonal occur at a distal range. Neuman envisioned this model as an open structure, applicable and adaptable to innumerable settings and patient populations by utilizing a whole client approach.

Study Design

This study was guided by the Whittemore and Knafl [21] modified framework for integrative review. This strategy enhances the rigor of integrative reviews by providing a framework for problem identification, literature search, data evaluation, and data analysis.[21] Once the problem was identified, thus defining the purpose of this integrative review, a literature search was conducted. Following extraction of relevant articles, data evaluation and analysis was conducted using the Neuman System model as a theoretical framework.

Methods

A search of the literature was conducted via PubMed, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Scopus. Inclusion criteria were 1) a study focus on tracheal suctioning, endotracheal suctioning, or endotracheal tube suctioning, 2) participant age < 18 years, and 3) original research, and availability in English language. Date limits were not set. Exclusion criteria were 1) literature that did not include developmental, psychological, or physiological effects associated with endotracheal suctioning as defined by the Neuman Systems Model; 2) studies with subjects ≥ 18 years of age; 3) literature reviews; and 4) manuscripts focused on clinician decision making or perceptions. The search initially used the key words *tracheal suctioning* or *endotracheal suctioning* or *endotracheal tube suctioning*, and *effects.* Three additional search terms were then added separately to the initial terms and searched in succession. These terms were *developmental*, *psychological*, and *physiological.* The search yielded 327 articles excluding duplications (Figure 1). The abstract of each article was reviewed to assess for inclusion in the sample. The full text was obtained if an abstract was not provided or if further clarification was required to determine inclusion. Seventy-three full text articles were reviewed for inclusion, ranging in publication date from 1981 to 2016. Thirty-six articles met inclusion criteria. Once the breadth of this research was determined, articles with a publication date of greater than ten years ago were excluded. The final sample included 14 studies reporting the developmental, psychological, and physiological effects of endotracheal suctioning in the pediatric patient and what populations of children have been included in the study samples in this area.

Results

The abstracted articles that met the inclusion criteria are described in Table 1. The research trials aligned into three groupings: neurovascular system, pulmonary system, and pain related to endotracheal suctioning. A Neuman Systems Model's principle is to consider the environmental interactions that can affect the client. As applied to this integrative review, suctioning is the central environmental stressor, and each trial examined the response to that stressor. Additional stressors are the client variables that are related to the disease processes or mechanisms of injury. Environmental influences include pain management and suctioning techniques. Four trials examined the effect of suctioning in pediatric patients, but only one included subjects over 18 months of age. The remaining trials were conducted on premature infants.

Neurovascular System

Five studies examined effects on the neurovascular system (Table 2.). Four studies examined the effect of endotracheal suctioning on cerebral blood flow velocity (CBFv) in premature infants.[22-25] Tume et al.[26] sought to determine the effect of nursing interventions, including endotracheal suctioning, on intracranial pressure (ICP) in 25 children with moderate to severe traumatic brain injury.

The first four studies examined the effect of endotracheal suctioning on very low birth weight premature infants (< 1,500 grams at birth). Preterm infants have immature cardiovascular regulation that puts them at risk for cerebrovascular injuries.[25] This risk factor related to prematurity is a component of the internal environment within the client, with intrapersonal stressors occurring within the cerebrovascular system.[20] Suctioning is an additional external environmental component causing interpersonal stress. Researchers were concerned that the hemodynamic changes that occur during suctioning could impair cerebral perfusion, resulting in cerebral injury. Rieger et al.[22] and Kaiser et al.[23] used transcranial doppler to assess CBFv (n= 167). Kaiser et al.[24] then compared CBFv during open suctioning to CBFv during closed suctioning. They reported no difference in CBFv, heart rate, pCo2, and oxygen saturation between the two suctioning techniques.

In 2008, and then in 2011, Kaiser et al. examined the effect of endotracheal suctioning on CBFv. Initially they reported a longer duration of increased CBFv than reported in previous studies, a median increase of 29.33% and return to baseline by 25 minutes following completion of suctioning. [23] There is evidence that increased CBF can be a factor in development of intraventricular hemorrhage, a source of morbidity for premature infants.[23] This data offered new information for practitioners caring for premature infants, demonstrating potentially adverse neurovascular effects associated with routine suctioning. Kaiser and colleagues[24] then examined changes in CBFv during open suctioning versus closed suctioning. Seventy-five infants were studied with 124 open suctioning events and 96 closed suctioning events. The authors determined the area under the receiver operating characteristic curve (AUC) for change in CBFv, with lower AUC being preferred. Closed suctioning was significantly lower (CBFv with p =.0003 and pCO_2 p = .0004). AUC for mean arterial pressure was not significant. [24]

Lastly, Limperopoulos and colleagues [25] examined systemic and cerebral circulatory changes during routine care, including endotracheal suctioning, in 82 premature infants. Cerebral hemodynamics were determined by near infrared spectroscopy (NIRS), spectrophotometer, and oxygen saturation. Researchers observed each infant continuously for up to 12 hours per day with 6 different care events recorded in 10-minute epochs. Endotracheal suctioning had a statistically significant effect on changes in mean arterial pressure, oxygen saturation, change in mean oxygen saturation, change in cerebral oxyhemoglobin (HbO_2), and deoxyhemoglobin (Hb) concentration.[25]

Tume, Baines, and Lisboa[26] asserted that children with closed head injury were typically treated with minimal handling to reduce likelihood of exacerbation of intracranial hypertension. Yet, patient care interventions must be performed to prevent morbidity during hospitalization. This study sought to determine the effect of routine endotracheal suctioning on intracranial pressure. Intracranial pressure changes are a combination of both internal and external environmental components.[20] The external component is the mechanism of the traumatic brain injury and the internal is the physiologic response to the injury. The injury creates an intrapersonal stressor with the endotracheal suctioning and additional interpersonal stressor. The client variable measured is physiologic. Endotracheal suctioning demonstrated a significant change from baseline to maximal ICP ($p < .001$). Maximal ICP to post-suctioning ICP was also significantly increased ($p < .001$). Treatment threshold of an ICP < 20mmHg was exceeded by 70% of children suctioned, and 28% of those also exceeded 30mmHg.[26]

Respiratory System

Three studies examined the effect of endotracheal suctioning (Table 3.) on the respiratory system.[27-29] The act of endotracheal suctioning is an external environmental factor that may produce intrapersonal stressors within the client.[20] The client variables that were measured were physiologic. The first two compared open versus closed suctioning techniques. Endotracheal suctioning can be performed in two ways: open, indicating the mechanical ventilator is disconnected from the endotracheal tube to insert a suction catheter, and closed, indicating suctioning occurs without disconnecting from the ventilator. Closed suctioning uses a multiple-use sterile catheter that is connected to the endotracheal tube via an additional port, thus eliminating the need to disconnect the mechanical ventilator. The third study examined changes in lung compliance.[28] Although suctioning is conducted to remove secretions and prevent atelectasis, some animal models have suggested lung compliance decreases endotracheal suctioning. This change in compliance can negatively affect the effectiveness of the mechanical ventilation.

Of the studies that focused on open versus closed suctioning, one trial included premature infants (n=59) and one trial consisted of pediatric patients, ages 0-18 years (n=229). Pirr et al.[29] conducted randomized crossover studies in which each premature infant received two suctioning events, one open and one closed. Oxygen saturation is reported as a percentage, with 100% being fully saturated. Normal oxygen saturation are 95-100% with <90% considered low.[30] The body requires adequate oxygenation in order to function properly; consequently, clinicians strive to prevent desaturation. Hypoxemia was defined in two tiers, as saturation at <85% and <80%, the lower saturation group exhibiting a more severe hypoxic episode.[29] Bradycardia was defined as heart rate <80 beats per minute.[29] Normal newborn heart rate is about 140 beats per minute with American Heart Association threshold for resuscitation at 100 beats per minute.[31] Closed suctioning showed statistically significant reductions in saturation < 85%, minimum saturation, maximum decrease in saturation, arterial oxygen saturation, and oxygenation ratio.[29] In the study conducted with pediatric patients, Evans et al.[27] collected data over a four-month period in all patients (0-18 years of age) intubated and receiving suctioning. Each month was designated as open or closed suctioning, for a total of two months with each technique. The sample included 229 patients with 6,691 suctioning events. With open suctioning, there was a statistically significant change in physiological parameters of decreased oxygen saturation (p = .01), increased mean arterial pressure ($p < .01$), and increased heart rate ($p < .01$).[27] A change of 20% was set as the cut-off for clinically significant change by the researchers. Frequencies of adverse events were similar between the two techniques, though closed suctioning resulted in increased endotracheal tube occlusion and open suctioning led to more accidental dislodgment of the endotracheal tube.[27] There were no other significant differences between open and closed suctioning in either study.

Morrow, Futter [28] examined the effect of endotracheal suctioning on lung dynamics in 78 pediatric patients, ages 0.3-25 months. They reported a statistically significant decrease in dynamic compliance and expired mechanical tidal volume immediately following endotracheal suctioning. The decrease in compliance was directly related to endotracheal tube and suction catheter size. Though a majority had a decrease in compliance (68.8%), compliance increased in 31.5% of patients. There was no significant change in inspiratory or expiratory airway resistance.[28]

Pain

Six trials assessed pain associated with endotracheal suctioning (Table 4). Pain can be affected by all client variables including physiologic, psychological, sociocultural, developmental, and spiritual. [20] The studies that met the inclusion criteria primarily measured physiologic variables. The external environment, suctioning, affects the internal environment of the client. The underlying illnesses may contribute to intrapersonal stress and the medical interventions may result in interpersonal stressors.[20] Of the three trials with premature infants (n=56), two evaluated the effects of non-pharmacological interventions of patient positioning to decrease stress and improve self-regulatory behaviors, and the third investigated a method for objective assessment of procedural pain.[32-34] The two studies that evaluated positioning techniques reported that pain scores and stress behaviors were decreased with intervention. Peyrovi and colleagues [34] demonstrated statistical significance in the change in heart rate between intervention and non-intervention groups. The intervention groups demonstrated less change in heart rate, indicating decreased hemodynamic effects associated with the pain and agitation related to suctioning. Cone et al.[32] reported an increase in oxygen saturation in the intervention group following suctioning compared to baseline oxygen saturation ($p < .001$); however, the increase had little clinical significance, as saturation increased from 95.49% to 97.75%.

The third study, reported by Karpe et al., [33] investigated a method for objective assessment of procedural pain. A skin conductance algesimeter is a device that measures changes in skin conductance due to sweat gland secretion in response to pain.[33] The release of moisture affects the conductance, allowing an objective measurement compared to a baseline reading when calm and pain free. The increase in conductance from baseline was statistically significant for both endotracheal suctioning and finger pricks for blood sampling at $p < .001$. Both interventions were painful, with finger prick more painful than suctioning, but the differences in the elevated scores (suctioning, finger prick) were not statistically significant from one another.[33]

Whereas three of the trials concentrated on premature infants, the remaining three studies encompassed children 0-18 years of age but predominantly infants and young children (n=162). Franck et al. [35] investigated infants less than 6 months of age following congenital heart surgery; Cury, Martinez, and Carlotti [36] enrolled infants and children less than 18 months of age; Sonmez Duzkaya and Kuguoglu [37] included children 1 month-18 years of age, with 67.6% four years of age or less. All three studies sought to evaluate pain and the validity of pain scales to detect the presence of pain. The studies confirmed that endotracheal suctioning is a painful procedure, and appropriate interventions including valid measurement tools should be employed to decrease pain levels.

Discussion

The purpose of this integrative review was to determine how studies reported the effects of endotracheal suctioning in the pediatric patient, and what populations of children have been included in the study samples in this area. Fourteen studies met the inclusion criteria and centered on three areas: effects in the neurovascular system, respiratory system, and the pain associated with endotracheal suctioning. A key finding of this study was that the majority of the studies (67%) examining the effects of endotracheal suctioning were conducted in the premature infant population. Only three studies in the premature population included race demographics in their results. Of these studies, race was diverse but enrollment only totaled 90 subjects. Furthermore, the most frequent topic was the experience of pain associated with endotracheal suctioning. However, half of those studies use suctioning as a proxy for painful procedures to validate pain assessment tools.[35-37]

The Neuman Systems Model includes five client variables: physiological, psychological, sociocultural, developmental, and spiritual. All of the studies explored the physiological effects, namely the effects within the organ and regulatory systems of the subjects. The physiological effects described included changes in cerebral blood flow velocity, oxygen saturation, heart rate changes, blood pressure and manifestations of pain.

Cone et al. [32] and Peyrovi et al. [34] investigated the use of positioning interventions to improve auto regulation as it is related to developmental immaturity but does not specifically examine the human growth and developmental transitions that occur over the lifetime.[20] The remaining client system variables of psychological, sociocultural, developmental, and spiritual have not been studied. These variables are more challenging to study in the younger patient population but are increasingly applicable as children grow and mature. Yet even young infants can have psychological effects from endotracheal suctioning. The current literature establishes that suctioning is a painful procedure and is likely performed multiple times during a hospitalization. The questions of what are the lasting effects of endotracheal suctioning and how do these stressors affect the client's created environment are left unanswered. Psychological effects may differ at different clients' ages and circumstances. Do these differences alter the effect of endotracheal suctioning? Are there cultural components, especially as children mature, which affect how this procedure is experienced? Do clinician cultural variables affect how suctioning is performed, and what actions are taken to decrease pain associated with the event? Children with chronic illnesses may experience suctioning during various developmental stages of their life. Furthermore, pediatric intensive care units care for children from birth until the cusp of adulthood. Developmental client variables are an important area in need of research. Spirituality is regarded as an essential component of complete nursing care.[38] There is not a uniform definition to spirituality in relation to client care, but frequently include recognition and support for a clients' spiritual needs when challenged with trauma, illness, or sadness. These needs can include the client, family and community.[38] How do the spiritual need of children and their families affect their experience of endotracheal suctioning? It would not be surprising to learn that children are saddened by their hospitalization. Does this stressor change the physiological response to a component of their external environment? These questions remain a gap in the literature.

The Neuman Systems Model also examines internal, external, and created environments.[20] The internal environment correlates with intrapersonal stressors. These are influences that occur only within the client. As all of these clients were hospitalized requiring intensive care management, it is likely that they were all experiencing intrapersonal stressors; however, these studies did not examine these changes compared to prehospitalization. Premature infants are known to have immaturity neurovascular and autoregulation areas but this was also not the focus of these studies. Moreover, many of the studies excluded children with congenital pulmonary, cardiac, or neurological defects as well as genetic abnormalities. These diagnoses affect the intrapersonal environment. Children with pulmonary or cardiac defects may not have normal physiological parameters at baseline. None of the studies investigated how these differences affected the response to endotracheal suctioning. Children with neurological or genetic abnormalities may also have intrapersonal stressors that affect their response. The external environment correlates with inter and extra-personal stressors. All of the studies examined the external environment related to interpersonal stressors, which are forces that occur at a proximate range e.g. endotracheal suctioning. Extrapersonal stressors, those that occur at a distal range, e.g. policies or financial pressures, have not been studied as those stressors may affect client variables. Evans et al.[27] measured frequency of suctioning events and nursing time when comparing open versus closed suctioning but nursing procedures factors were not correlated with changes in client variables. Research examining the effect of policies and procedures is an area in need of research. System issues that may result in extrapersonal stressors were not examined. The created environment is unconsciously developed by the client and employs both internal and external environment components. The purpose of the created environment is to provide "protective, perceptive coping" in response to stressors.[19] These coping mechanisms as related to the experience of endotracheal suctioning in pediatric populations have not been studied.

Conclusion

This integrative review demonstrates that, despite the seemingly general acknowledgment of adverse effects from suctioning, literature examining the physiological effects in the pediatric population is limited. Endotracheal suctioning is routinely performed in pediatric intensive care units. Clinicians are educated on practice recommendations, e.g. preoxygenation, indication and frequency of suctioning, suctioning catheter depth, and use of saline irrigation. [18,39] Furthermore, adverse sequalae of suctioning are cited as basis for practice recommendations. The adverse effects include respiratory, cardiovascular, and neurologic complications. The majority of the recent literature is in the premature population, revealing a gap in the literature. Research is needed investigating the effects in older infants, toddler, school age, and adolescent pediatric patients. The physiologic effects of oxygen saturation, heart rate and blood pressure were used as measurement variables, but none of the studies examined the etiology of the physiologic changes. Moreover, most of the studies excluded children with congenital cardiac or pulmonary defects, neurological injury or genetic syndromes. Research in children in these complex, vulnerable populations is limited. Additional research is needed to examine the cardiopulmonary alterations that occur in response to interruptions in mechanical ventilation, introduction of airway suction, and the ensuing pain associated with endotracheal suctioning. The gaps identified in the literature include pediatric age groups beyond the newborn period, in addition to children with congenital cardiac or pulmonary defects, neurological injury or genetic syndromes. Research is also needed to examine the psychological, sociocultural, developmental and spiritual client variables throughout the age span.

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Table 1. Integrative Review Manuscripts – All Categories

Pain during Suctioning – Premature Infants

Title	Objective	Setting	Study Design	Methods	Results
Peyrovi, H., Alinejad-Naeini, M., Mohagheghi, P., & Mehran, A. (2014).	Study evaluated effect of facilitated tucking on procedural pain from endotracheal suctioning	34 premature infants in Level II Neonatal Intensive Care Unit in Iran.	Randomized controlled crossover study	Two suctioning events spaced two days apart	Average time to achieve pain score of one and change in oxygen saturation were not statistically significant. Change in heart rate was significant (p =.013).
Cone, S., Pickler, R. H., Grap, M. J., McGrath, J., & Wiley, P. M. (2013).	Evaluate four-handed care on infants' physiological and behavioral response and recovery from endotracheal suctioning	10 premature infants in neonatal intensive care unit in an academic health center in the United States	Randomized controlled crossover study	Each subject was randomized to receive either routine suctioning or four-handed suctioning. Each infant was observed twice in a single day in the first week of life	Intervention group oxygen saturation increased ($p < .001$). There was no difference from baseline HR, SpO_2, cortisol level. Infants demonstrated more self-regulatory behaviors with four-handed suctioning
Karpe, J., Misiolek, A., Daszkiewicz, A., & Misiolek, H. (2013)..	Evaluate objective assessment of pain during selected procedures including endotracheal suctioning	32 premature infants in neonatal intensive care unit in Poland	Observational Trial	Skin conductance algesimeter were used to measure sympathetic nervous system activation by pain stimulus	Pain measured from endotracheal suctioning and finger tip puncture were both statistically significant at $p < .001$

Pain during Suctioning – Pediatric Patients

Title	Objective	Setting	Study Design	Methods	Results
Franck, L. S., Ridout, D., Howard, R., Peters, J., & Honour, J. W. (2011).	Compare pain indices representing behavioral, cardiorespiratory, and neuroendocrine	81infants following cardiac surgery	Observational trial	Physiologic, endocrine measures and four composite pain scales measured during various painful procedures	COMFORT score performed best (p < .0001)
Cury, M. R., Martinez, F. E., & Carlotti, A. P. (2013).	Test convergent validity of COMFORT scale and Cardiac Analgesic Scale (CAAS) in response to endotracheal suctioning	16 neonates and infants (<18 months of age) prospectively assessed during endotracheal suctioning on days 1-3 following cardiac surgery	Observational trial	Pain was assessed using both COMFORT and CASS scale before and during endotracheal tube suctioning once daily for up to three days	Correlation between CAAS and COMFORT (p = .0002). Pulmonary artery pressure significantly increased (p = .04)
Sonmez Duzkaya, D., & Kuguoglu, S. (2015).	Two-level study to evaluate pain during endotracheal suction	65 patients in PICU age 1-18 years of age. 18 PICU nurses in Turkey	Two phases – descriptive and comparative. Aim to assess pain in the PICU	Data regarding pain assessment using FLACC pain assessment and Wong-Baker Faces pain rating scale	Both groups demonstrated pain with endotracheal suctioning with no statistical difference between groups

Trials Comparing Open versus Closed Suctioning Technique – Premature Infants

Title	Objective	Setting	Study Design	Methods	Results
Pirr, S. M., Lange, M., Hartmann, C., Bohnhorst, B., & Peter, C. (2013).	Evaluate whether closed suctioning decreases frequency of hypoxemia and bradycardia	15 extremely low birth weight neonates in the neonatal intensive care unit of a tertiary hospital in Germany	Randomized controlled crossover study	Each subject was randomized to either begin with open or closed suctioning. Suctioning was repeated four hours later with opposite technique	In the primary outcome there was a statistically significance in incidence of hypoxemia, saturation < 85% (p = .012), minimum saturation (p =.012), maximum decrease in saturation (p = .007)

Trials Comparing Open versus Closed Suctioning Technique – Pediatric Patients

Objective	Setting	Study Design	Methods	Results
Compare open and closed suctioning from a physiological, safety, and staff resource perspective	258 subjects with 6691 suctioning events	One suctioning technique employed on all patients for 2 of 4 months, alternating	Data collection completed by performing nurse after every suctioning event	Closed suctioning had less incidence of decreased oxygen saturation (p = .01), increased MAP (p < .010), increased HR (p < .01)

Trials examining Cerebral Blood Flow Velocity (CBFv) during Endotracheal Suctioning – Premature Infants

Title	Objective	Setting	Study Design	Methods	Results
Rieger, H., Kuhle, S., Ipsiroglu, O. S., Heinzl, H., & Popow, C. N. (2005).	Investigate if the mode of suctioning or mechanical ventilation affects CBFv in ELBW infants	19 infants in the first two weeks of life in neonatal intensive care unit in Austria	Observational study	Transcranial Doppler sonography during OS and CS in conventicle and high frequency ventilation. Total of 41 measurements were performed	No significant differences were seen CBFv, heart rate, transcutaneous pCO2, oxygen saturation
Limperopoulos, C., Gauvreau, K. K., O'Leary, H., Moore, M., Bassan, H., Eichenwald, E. C., . . . du Plessis, A. J. (2008).	Examine systemic and cerebral circulatory changes during routine events in critical care of preterm infants	82 infants in tertiary neonatal intensive care unit in the United States.	Observational study	Continuous mean arterial blood pressure (MAP), near-infrared spectroscopy (NIRS), cerebral oxyhemoglobin (HbO2), and deoxyhemoglobin (Hb) concentration and oxygen saturation (SaO2)	Endotracheal suctioning had a statistically significant effect on change MAP, SaO2, change in mean SaO2, change in Hb difference and total HBHb.
Kaiser, J. R., Gauss, C. H., & Williams, D. K. (2008).	Examine the effects of tracheal suctioning on cerebral hemodynamics of very low birth weight infants (VLBW)	73 VLBW in neonatal intensive care unit in the United States	Observational study	B/P, PaCO2, PaO2, and CBFv were continuously monitored before, during and after suctioning for first week of life up to twice daily for DOL 1-3 and once daily for DOL 4-7	Increase in CBFv was longer than previously described. Time to peak CBFv was 11.4 ± 11.6 minutes following suctioning. Median percent change was 29.3%

Title	Objective	Setting	Study Design	Methods	Results
Kaiser, J. R., Gauss, C. H., & Williams, D. K. (2011).	Examine the effects of open suctioning (OS) plus intermittent mandatory ventilation (IMV) compared to closed suctioning (CS) plus volume guarantee (VG) ventilation on mean cerebral blood-flow velocity	75 very low birth weight infants in neonatal intensive care unit in the United States	49 infants received open suctioning and IMV. 26 infants received CS and VG	Cerebral blood flow velocity, transcutaneous pCO2, and blood pressure were monitored before, during and after tracheal suctioning for the first week of life	The CS + VG for cerebral blood flow velocity AUC was significantly lower at *p*= .0003. The AUC for pCO2 was significantly less for the CS + VG at *p* = .0004. AUC for mean arterial pressure was not significant

Trial of Effect of Endotracheal Suctioning on Lung Dynamics – Pediatric Patients 0.3-25 months

Title	Objective	Setting	Study Design	Methods	Results
Morrow, B., Futter, M., & Argent, A. (2006).	Determine the immediate effect of endotracheal suctioning on expired tidal volume, compliance, and airway resistance	78 patients in pediatric intensive care unit in South Africa. Inclusion: Mechanical ventilated with endotracheal tube ≤ 4.0mm internal diameter	Observational study	Dynamic compliance, inspiratory airway resistance, expiratory airway resistance, ETT leak, mechanical expired tidal volume, spontaneous expired tidal volume, respiratory rate, total minute volume were measured	Significant decrease in dynamic compliance ($p < .001$), and mechanical expired tidal volume ($p = .03$). No significant change in expiratory or inspiratory airway resistance

Trial of effect of Suctioning on Intracranial Pressure – Pediatric Mean age 9.4 years (SD 4.5)

Title	Objective	Setting	Study Design	Methods	Results
Tume, L. N., Baines, P. B., & Lisboa, P. J. (2011).	Determine the effect on certain nursing interventions on intracranial pressure in children with moderate	25 children with moderate to severe traumatic brain injury requiring intraparenchymal	Prospective observational trial in a tertiary pediatric intensive care unit	Five nursing interventions were studied: endotracheal tube suctioning with manual ventilation, log rolling,	Endotracheal suctioning demonstrated a significant change from baseline to maximal ICP (p <.001) as well as maximal to post ICP (p

	to severe traumatic brain injury	intracranial pressure monitoring in England		eye care, oral care and bathing	<.001)Determine the effect on certain nursing interventions on intracranial pressure in children with moderate to severe traumatic brain injury

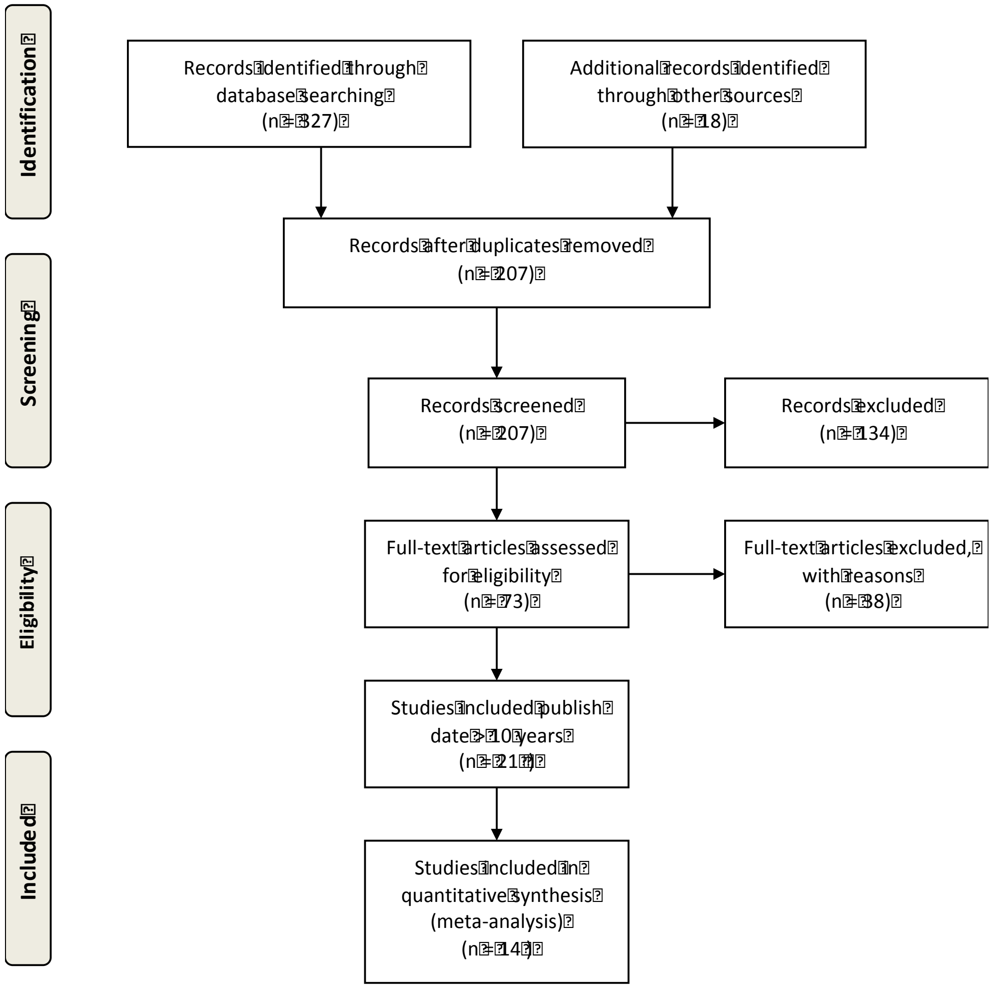

Figure 1. Prisma Flow Diagram of Literature review

Table 2. Neurovascular System

Author	Age Group	Age	Sample Size	Male	Race	Outcome
Tume	Pediatric	Median 9.4 years (SD 4.5)	25	15	Not reported	Intracranial Pressure
Rieger	Premature	2-14 days	19	Not reported	Not reported	Cerebral Blood Flow Velocity
Limperopoulos	Premature	0-5 days	82	42	Not reported	Cerebral Blood Flow Velocity
Kaiser (2008)	Premature	0-7 days	73	31	54% Caucasian, 38% African American, 8% Hispanic	Cerebral Blood Flow Velocity
		0-7 days Cohort 1	49	21	33% Caucasian, 12% African America, 55% Hispanic	
Kaiser (2011)	Premature	0-7 days Cohort 2	49	21	33% Caucasian, 12% African American, 55% Hispanic	Cerebral Blood Flow Velocity

Table 3. Pulmonary System

Author	Age Group	Age	Sample Size	Male	Race	Outcome
Pirr	Premature	< 30 days	15	7	Not reported	Suctioning Technique
Evans	Pediatric	0-18	258	Not reported	Not reported	Suctioning Technique
Morrow	Pediatric	0-25 month	41	Not reported	Not reported	Lung Dynamics

Table 4. Pain

Author	Age Group	Age	Sample Size	Male	Race	Outcome
Peyrovi	Premature	1 wk, 2 wk, >2 wks	34	18	Not reported	Pain
Cone	Premature	1 wk	10	6	70% African American, 30% Caucasian	Pain
Karpe	Premature	<7 days	32	Not reported	Not reported	Pain
Franck	Pediatric	< 21 days	81	53	Not reported	Pain

Author	Age Group	Age	Sample Size	Male	Race	Outcome
Cury	Pediatric	4-410 days	16	7	Not reported	Pain
Sonmez Duzkaya	Pediatric	1-12 mo, 2-4 y, 5-8 y, 9-12 y, >13y	65	42	Not reported	Pain

Instruments for Risk Adjustment in Congenital Heart Disease: An Integrative Review

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Abstract

Congenital heart disease is inclusive of many diverse diagnoses and more than 100 types of operative procedures. This heterogeneity results in a challenge for any one center, even high volume centers, to have a sufficient volume of any particular diagnosis or surgical procedure to assess outcomes, quality or care, or impact of interventions. It is necessary to tools to measure and compare cases across institutions locally, nationally, and internationally. This integrative review was conducted to identify tools that can be used to risk adjust for surgical risk of mortality. A literature search was conducted to identify risk adjustment measurement tools. Inclusion criteria were congenital heart disease, age < 18 years, mortality risk, and availability in English. Exclusion criteria were tools for non-surgical CHD procedures, or tools intended for adults with CHD. Six tools were identified with differing areas of emphasis: complexity of surgical procedure (Risk Adjustment for Congenital Heart Surgery [RACHS-1], Aristotle Basic Complexity score [ABS], and Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery [STAT]), postoperative physiologic markers (Vasoactive Inotrope Score [VIS]), and success of surgical technical performance (Technical Performance Score [TPS]). RACHS-1, TPS, and STAT demonstrated high prediction for risk of mortality; with RACHS-1 with the greatest predictability and STAT able to predict more surgical types. VIS is a newer tool with a c-statistic of >0.80. TPS demonstrated p <0.001 as an independent predictor of mortality.

Key words: congenital heart disease, risk adjustment; cardiac surgery

Instruments for Risk Adjustment in Congenital Heart Disease: An Integrative Review

Introduction

Over 33,000 surgeries for congenital heart disease (CHD) are performed annually, predominantly on children.[40] Compared to adult cardiac surgery, surgery for CHD includes relatively few cases with a higher number of operative types.[41] In fact, more than 100 different types of operative procedures are used for CHD, making risk adjustment in congenital heart surgery challenging. These cases have significant heterogeneity, ranging from simple to very complex. As complexity increases, mortality increases. At the same time, however, assessing the quality of care in congenital heart disease requires a certain degree of homogeneity in order to compare and measure cases across institutions, countries, and time.[42]

Theoretical Framework

Knowledge-to-Action provided the theoretical framework to address the need to compare CHD mortality risk in various settings.[43] Knowledge-to-Action has three phases (Figure 1): knowledge inquiry, synthesis of knowledge, and development of knowledge tools in response to an identified problem.[44] In congenital heart disease, the identified need is the ability to compare interventions and outcomes across centers. Surgical risk adjustment represents the risk of mortality for a given surgical procedure. Institutions may differ on which cases are the highest risk in their patient population, but a risk adjustment tool allows for evaluation of comparable cases across institutions. Comparing outcomes among centers allows for greater knowledge to compensate for the small volume of cases at individual centers. This knowledge can then be put into action when assessing current literature, designing new research, selecting interventions, and evaluating outcomes. An integrative review was conducted to identify tools that can be used to compare surgical risk of mortality across institutions.

Methods

A literature search was conducted to identify risk adjustment measurement tools. Inclusion criteria were congenital heart disease, age < 18 years, mortality risk, and availability in English. Exclusion criteria were tools for non-surgical CHD procedures, or tools intended for adults with CHD. Literature was searched via PubMed, Cumulative Index to Nursing and Allied Health Literature, and Scopus using the key words *congenital heart disease* and *risk categories* (Figure 2). PubMed yielded 175 citations and Scopus 3 citations. Cumulative Index to Nursing and Allied Health Literature yielded 5 citations that did not meet inclusion criteria. The search term *risk categories* were modified to *risk stratification*, producing 24 additional citations. A review of reference lists identified an additional eight citations. A total of 214 non-duplicated citation abstracts were reviewed, and 31 were extracted for further review. Four additional articles were excluded during review of full texts and two more during data extraction as they did not meet inclusion criteria. Following this search, 25 articles were included in the final integrative review.

Results

Five tools identified in the review measured and stratified risk for mortality following CHD surgery. Early methods were based on expert opinion and consensus as large multi-institutional datasets were not available at that time. The Risk Adjustments for Congenital Heart Surgery category and Aristotle Basic Complexity score were the first attempts to group the numerous CHD surgical procedures into categories with similar risks of mortality.[42,45,46] Procedures were independently ranked in severity by expert panelists. Interrater reliability was established during subsequent meetings of each work group, and final group designations were established. Later methods were developed by analysis of empirical data from large national and international data sets.[47-49] The Vasoactive Inotrope Score tool utilizes the level of postoperative support as a measure of risk of mortality. Lastly, an initial quality improvement initiative by Karamichalis et al. has continued to develop and is now a measurement tool to predict postoperative risk of mortality.[50] The Technical Performance Score measures specific surgical performance outcomes to determine risk of mortality.[51-54]

Risk Adjustment for Congenital Heart Surgery

The Risk Adjustment for Congenital Heart Surgery risk stratification tool was developed by an 11-member expert panel of cardiologists and cardiac surgeons.[45] This tool was created with the specific intention to allow comparison across institutions. The panel grouped 207 surgical procedures into categories representing similar risk of in-hospital mortality. Risk category one represented the least risk of mortality, and risk category six represented the highest risk of mortality. Each panel member categorized the procedures individually then brought the results to the group for discussion and revision, establishing interrater reliability as the tool was developed. Intrarater reliability was established using the International Classification of Diseases, Ninth Revision, *Clinical Modification* and *Current Procedural Terminology 4*. The resultant six groupings were then tested for accuracy using data from two large multi-institution data sets. The first data set was from the Pediatric Cardiac Care Consortium, which collects data from 32 institutions for cardiac procedures on children younger than 18 years of age. The second data set was data from three states during two years (Illinois 1994, Massachusetts 1995, California 1995). The models developed reported the area under the receiver-operator characteristic (ROC) curve or c-statistic (Table 1). The c-statistic characterizes how well the model determines risk of mortality between patients.[45] A value of 0.50 indicates no discrimination and 1.0 indicates perfect prediction. Greater than 0.80 is considered good and greater than 0.90 is considered excellent. The Pediatric Cardiac Care Consortium data had a c-statistic of 0.811, and the hospital data set had a c-statistic of 0.814 in a model that included age at time of surgery, prematurity, major chromosomal anomalies, and risk category designation. The c-statistic for the risk category alone was 0.784 for the Pediatric Cardiac Care Consortium data and 0.749 for the hospital data.[45] These results indicate that Risk Adjustment for Congenital Heart Surgery has good discrimination for risk of mortality.

This model has been applied to other international data sets with varied results. A data set from a large German hospital contained 3,064 procedures on children younger than 18 years. The Risk Adjustment for Congenital Heart Surgery model was applied. The authors did note a rising mortality in risk category 2 compared to the Pediatric Cardiac Care Consortium data in their data set; however, the c-statistic for the procedure alone was 0.755.[55] A Danish study analyzed 1,019 procedures in 889 children 15 years and younger.[56] The area under the ROC curve was 0.741. Japanese researchers analyzed both in-hospital and 90-day mortality. The database used contained data on 8,923 procedures from 64 sites.[57] The results indicated a c-statistic of 0.77 on in-hospital mortality; the 30-day and 90-day mortality was 0.73, 0.73, respectively.[57] Reliability was demonstrated, with the c-statistic remaining stable over repeated measurements, including those following discharge.

Researchers in the United States applied Risk Adjustment for Congenital Heart Surgery to a high-risk population of 114 newborns under 15 days of age requiring congenital heart surgery. In this sample, risk category 4 had a 1.5 increased odds ratio compared to those in risk category 6, and risk category 2 had an increased odds ratio of 6 compared to risk category 3.[58] The c-statistic was not reported.

Studies performed in developing nations or those with decreased access to surgical care found the Risk Adjustment for Congenital Heart Surgery was easily applied but did not correlate with their mortality outcome.[59,60] The decreased ability to predict mortality was attributed to multiple confounders, including decreased access to care and late presentation for intervention, decreased resources, and a developing surgical program. Risk Adjustment for Congenital Heart Surgery is an easily applied tool with high validity to predict mortality in developed countries but less evidence of validity in developing countries or specific patient groups with confounding factors affecting risk of mortality.

Aristotle Score

The Aristotle basic complexity score was developed by consensus of 50 cardiac surgeons and represents three components of potential for morbidity, mortality, and technical difficulty.[42,61,62] Also developed was the Aristotle Comprehensive Complexity score. The Aristotle Comprehensive Complexity score incorporated patient specific data and scored combined procedures (Table 2). Validity was tested using data from the European Association of Cardiothoracic Surgery registry containing 17,838 surgeries in

56 centers and data from the Society of Thoracic Surgeons database containing 18,024 surgeries in 32 centers.[46] The c-statistic was 0.70 for mortality; this improved to 0.73 in single procedure surgeries.[46] Aristotle Basic Complexity score ranked more patients than Risk Adjustment for Congenital Heart Surgery and demonstrated acceptable discrimination for risk of mortality.

Sinzobahamvya et al. examined 39 infants following Norwood Stage I palliation for single ventricle physiology at a single center in Germany.[63] Aristotle Comprehensive Complexity scores were calculated for all enrolled subjects. As noted earlier, Aristotle Comprehensive Complexity score includes patient factors in the calculation. The most frequent patient level factors were aortic atresia, interrupted aortic arch, preoperative mechanical ventilation, and preoperative shock that resolved prior to surgery.[63] In-hospital mortality was 58.8% for those with an Aristotle Comprehensive Complexity score of 20 compared to 9.1% for those with an Aristotle Comprehensive Complexity score of less than 20 (p=0.0014). The risk of mortality continued with similar results for one-year survival. Those with an Aristotle Comprehensive Complexity score of 20 or greater had a much lower survival than those with Aristotle Comprehensive Complexity score less than 20 (p <0.001). Results indicated a correlation of Aristotle Comprehensive Complexity score with early mortality as well as one-year survival. Additionally, the results reflect the influence of preoperative factors and surgical timing to mortality.

A retrospective analysis of 1,368 index operations in a single center in France tested Aristotle Comprehensive Complexity score results compared to their outcomes for mortality.[64] All subjects were less than 18 years of age except one. The results indicated strong correlation of Aristotle Comprehensive Complexity score and mortality with R^2

=0.24 and *p* <0.001. Reliability was reported with a c-statistic of 0.819. Aristotle Comprehensive Complexity score demonstrates good discrimination to predict mortality after surgery for congenital heart disease, though study limitations included having a small sample size from a single institution.

Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery

The Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery (STS-EASCTS) mortality score also utilized surgical procedures as the basis for risk stratification but used empiric evidence from two large surgical datasets to determine risk categories.[49] Outcomes of nearly 80,000 surgical procedures were analyzed, and risk was estimated in 148 procedures to create a Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery score (Table 3). The procedures were then grouped into one of five risk categories to create the Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery category. This number of categories was the fewest number possible while maintaining maximal homogeneity within the category. Category 1 represents the lowest risk of mortality, and category 5 represent the highest risk of mortality. A validation sample of all procedures with more than 40 occurrences (n=20,042) was performed and demonstrated a c-statistic of 0.787 for Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery Score, 0.778 for Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery Category compared to 0.745 for Risk Adjustment for Congenital Heart Surgery and 0.795 for Aristotle Basic Complexity score.[49] The strength of the Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery was its reliance on empirical data rather than subjective expert opinion. Results by O'Brien et al. demonstrated improved discrimination of mortality compared to Risk Adjustment for Congenital Heart Surgery and slightly less than Aristotle Basic Complexity score.[49] Individual procedure types were also analyzed. Procedures with more than 200 cases in the dataset had a Pearson correlation coefficient of >0.999, indicating nearly perfect correlation of the model estimates with actual results.[49] Further analysis was conducted with a subset of procedures that could be assigned all three tools: Risk Adjustment for Congenital Heart Surgery, Aristotle Basic Complexity score and Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery. Highest discrimination was for the Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery score (c=0.787), then Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery category (c=0.778), Risk Adjustment for Congenital Heart Surgery (c=0.745), and Aristotle Basic Complexity score (c=0.687) (O'Brien et al., 2009). All differences between tools were significant with $p<0.001$. This initial publication of a new risk stratification tool demonstrated high discrimination for mortality. Despite being based on empiric evidence, the results' implications are limited by being obtained from a voluntary dataset that did not include all centers; moreover, some procedures had small sample sizes.

Jacobs et al. analyzed 58,506 procedures from 73 institutions on patients less than 18 years of age entered into the Society of Thoracic Surgeons congenital heart surgery database.[48] The same tool was used, but was now renamed the Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery (STAT) mortality score. Funnel plots were generated, demonstrating that most centers were in the limits of 95% prediction. The few outliers identified support the discrimination of the tool. The grouping of cases with those of similar risk allowed for increased volume for analysis as individual procedures with higher risk were performed too infrequently for analyses.

Vasoactive Inotrope Score

The Vasoactive Inotrope Score tool examined postoperative inotrope infusion requirements to estimate risk of mortality (Table 4). Dosages of infusing inotropes are each transformed to have equal weight, and then combined to create a whole number score.[65] The scores are then assigned to one of five risk categories. Vasoactive Inotrope Score was calculated for 174 infants 6 months of age or less for the first 48 hours following surgery. Analysis demonstrated a Vasoactive Inotrope Score maximum and mean with c-statistics of 0.83 and 0.82, respectively. The cut point for high and low Vasoactive Inotrope Score and risk of mortality was determined to be category 4, with sensitivity of 0.71 and specificity of 0.80. High maximum Vasoactive Inotrope Score was associated with an 8.1 increased odds ratio of poor outcome. Postoperative recovery varies patient to patient; thus, Vasoactive Inotrope Score allows for striation of similar illness severities and ability to predict outcomes. This information can be used to guide care as well as for measurement in future research.

Davidson et al. sought to validate Vasoactive Inotrope Score in a prospective study of 70 infants, 90 days of age or younger.[66] Though poor outcome or mortality was one of the outcome variables, the rate was too low for accurate calculation; therefore, prolonged intubation was used as a primary outcome. Vasoactive Inotrope Score was calculated at 24 hours, at 48 hours, and maximum during the 48 hours. Vasoactive Inotrope Score had a c-statistic of 0.90, 0.93 and 0.88, respectively.[66] Nine patients met criteria for poor outcome, with two dying prior to 48 hours. This affected the ability to analyze this group, but Vasoactive Inotrope Score had moderate association with the poor outcome, at an odds ratio of 6 and *p* value of 0.076.[66] As a newer tool, Vasoactive Inotrope Score has not been researched extensively but has shown to be an effective tool for future research to stratify patients with similar postoperative risk.

Technical Performance Score

The final tool reviewed is a measurement of intraoperative technical performance (Table 5). First designed as a quality improvement project to critique surgical outcomes, it was refined and demonstrated discrimination for risk of mortality.[50] This Technical Performance Score assesses the adequacy of surgical repair as determined by specific echocardiographical measurements.[51] Repairs were placed in one of three performance categories: optimal, adequate or inadequate. The initial analysis included 185 patients less than 18 years of age in a single center. Technical Performance Score demonstrated a strong association with mortality ($p < 0.001$). Nathan et al. also examined late mortality in 166 infants six months of age and younger followed for one year following surgery.[52] Inadequate Technical Performance Score was associated with late mortality with an odds ratio of 7.2 and $p < 0.001$.[52] These results support the need for early assessment of Technical Performance Score and reintervention for inadequate surgical repairs.

Nathan et al. (2013) also conducted a retrospective chart review of 725 patients, with 52 being greater than 18 years of age.[53] The team followed long-term outcomes in which 679 patients survived to discharge and 409 survived four years. Analysis of age, Technical Performance Score, Risk Adjustment for Congenital Heart Surgery designation, and Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery category were significant for mortality with $p<0.001$. These results support

Technical Performance Score discrimination as a predictor for mortality. These results were replicated in 1,926 procedures in 1,714 patients 0-68 years of age (211, 11% were adults), with a median age of 1.8 years.[54] Technical Performance Score again demonstrated significant association with mortality (p <0.001). Cases with class 3 performance scores (inadequate) had an odds ratio of 16.9 (p <0.001). These results indicate that inadequate Technical Performance Scores are associated with early as well as late mortality. This information encourages early reintervention, as risk of mortality is still present despite an ability to recover sufficiently to be discharged from a hospital.

Comparison Studies

Kang, et al. compared the results of the Aristotle Basic Complexity score and Risk Adjustment for Congenital Heart Surgery in a single center data set of 1085 surgeries in children less than 18 years of age (Table 6).[67] Due to the differences in the two tools, 98.4% of cases could be assigned an Aristotle Basic Complexity score compared to 92% able to be assigned a Risk Adjustment for Congenital Heart Surgery designation.[67] Analysis was performed on the 992 cases that were able to be categorized with both tools. Risk Adjustment for Congenital Heart Surgery demonstrated strong association with mortality (p = < .001) while Aristotle Basic Complexity score was less strongly associated with mortality (p = .03).

Al-Radi et al. analyzed 11,438 surgeries that could be assigned both Aristotle Basic Complexity score and Risk Adjustment for Congenital Heart Surgery categories in a single institution.[68] Their results were similar to Kang and colleagues because more patients were able to be assigned Aristotle Basic Complexity score categories but Risk Adjustment for Congenital Heart Surgery demonstrated better prediction of mortality.

Risk Adjustment for Congenital Heart Surgery demonstrated a likelihood ratio of x^2 13.4 with a p <.001 in contrast to Aristotle Basic Complexity score with x^2 of 162 and p =.009. Validity for each tool was calculated as a c-statistic of .763 for Risk Adjustment for Congenital Heart Surgery and .737 for Aristotle Basic Complexity score. This sample from a single Canadian center determined Risk Adjustment for Congenital Heart Surgery had better predictive ability.

Another analysis compared Risk Adjustment for Congenital Heart Surgery and Aristotle Basic Complexity score using the Society of Thoracic Surgeons database, again demonstrating Aristotle Basic Complexity score could categorize more operations (85.8 vs 94%), but Risk Adjustment for Congenital Heart Surgery had better discrimination.[41] The Society of Thoracic Surgeons database contained 45,635 cases in patients less than 18 years of age from 47 centers in North America. The c-statistic for Risk Adjustment for Congenital Heart Surgery was 0.743 and with Aristotle Basic Complexity score was 0.70. A model that included clinical factors improved the discrimination of Risk Adjustment for Congenital Heart Surgery to c-statistic of 0.814 and increased Aristotle Basic Complexity score to 0.74.[41] The authors advocated for a new tool combining the benefits of each.

Comparison analyses of risk stratification tools were also conducted in developing nations. One analysis consisted of 230 children 15 years of age of less in a medium-sized hospital in Thailand.[69] Despite the small sample size, the c-statistic results were similar to the larger studies in developed countries. The c-statistic for Risk Adjustment for Congenital Heart Surgery, Aristotle Basic Complexity score, and Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery were 0.78, 0.74 and 0.67, respectively. A prospective analysis conducted in India consisted of 1,312 patients less than 18 years of age.[70] In this study, Risk Adjustment for Congenital Heart Surgery was best able to discriminate for mortality (c-statistic of 0.7654), though the sample did not contain any patients with category 5 or 6 designation. Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery had a c-statistic of 0.75 but also did not contain any patients in the highest risk category, five. Another retrospective study in India included 1,150 patients less than 18 years of age. The Aristotle Comprehensive Complexity score demonstrated the best discrimination with a c-statistic of 0.704 compared to Aristotle Basic Complexity score of 0.677 and Risk Adjustment for Congenital Heart Surgery of 0.607.[71] Aristotle Comprehensive Complexity score had the best discrimination; however, actual mortality was significantly higher than other published studies at 7.91%. Though all three tools demonstrated acceptable discrimination, Aristotle Comprehensive Complexity score includes patient factors that improved its discrimination. There are multiple confounding variables that affect mortality risk in developing countries, such as age at time of surgery, nutrition, diagnosis stage, and, in this Indian population, percentage of cases with pulmonary hypertension.[71] These comparison studies demonstrate similar results as the non-comparison studies.

Reliability

Risk Adjustment for Congenital Heart Surgery and the Aristotle Basic Complexity score were developed based on expert consensus. Surgical procedures were grouped by similarity of risk. The Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery score was devised through empirical analysis of existing surgical databases. Its performance was compared to Risk Adjustment for Congenital

Heart Surgery and Aristotle Basic Complexity scores, and it yielded similar risks of mortality. Statistical analysis of reliability was not reported. Types of surgical procedures were determined by the International Classification of Diseases, ninth revision (ICD-9), as recorded upon hospital discharge or by an attending surgeon. An Aristotle Comprehensive Complexity score of 20 or greater had a mortality rate of 58.8% compared to 9.1% for Aristotle Comprehensive Complexity score <20.[63] Aristotle Comprehensive Complexity score had a Pearson coefficient of 1, a perfect correlation in a large sample in Germany.[72] Bojan, et al. also noted high correlation with the Aristotle Comprehensive Complexity score.[64] Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery score reliability was demonstrated through funnel plot analysis with most centers falling within the 95% limits of prediction across 73 centers.[48] The vasoactive inotrope score had high sensitivity and specificity to identify poor outcomes and high odds ratios for poor outcomes.[65,66] Inadequate technical performance scores were also strongly associated with mortality. Technical Performance Score of 3 (inadequate repair) had a 16.9 odds ratio compared to a Technical Performance Score of 1 (optimal).[51]

Validity

Risk Adjustment for Congenital Heart Surgery, Aristotle Basic Complexity score, Technical Performance Score, and Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery scores were validated utilizing large data sets of CHD surgery outcomes over numerous centers.[45,46,49,55-57,63,64,73] These measurement tools yielded a c-statistic of 0.70 or greater for discrimination of risk for mortality. The vasoactive inotrope score demonstrated a c-statistic of 0.83 for the maximum Vasoactive

Inotrope Score in its initial publication.[65] This work was replicated by Davidson et al. and yielded c-statistics ranging from 0.88-0.93 across the time points tested.[66] Technical Performance Score was associated with mortality with a *p* value of <0.001 across several studies.[50,52-54,74] Comparison studies also demonstrated acceptable c-statistics for the various mortality tools of Risk Adjustment for Congenital Heart Surgery Aristotle Basic Complexity score, Aristotle Comprehensive Complexity score, and Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery.[41,68-71]

Discussion

Risk stratification tools allow for case-mix adjustment of outcome data. The case-mix index is essential to assess quality of care, compare research outcomes and to have a common language across institutions performing CHD surgery. The Risk Adjustment for Congenital Heart Surgery and Aristotle basic case complexity scores are still widely used in the literature. The validity of these tools has been demonstrated in multiple studies. Risk Adjustment for Congenital Heart Surgery has been shown to have better discrimination in the higher risk categories while the Aristotle Basic Complexity score was able to classify more types of surgical procedures. The Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery score seeks to utilize the advantages of striation based on complexity of surgical procedure but emphasizes the use of empiric data and eliminates the inherent subjectivity when relying on expert opinion. Inotrope-based scores are easily calculated in real time, but comparison across institutions may be problematic due to variations in institutions' postoperative inotrope practices with similar acuities. The differences in practice as evident in the Vasoactive Inotrope Score may not represent actual differences in postoperative risk of mortality.

The two published studies demonstrated correlation of high maximum vasoactive inotrope score with poor outcomes. Current use of the Technical Performance Score calculates performance with echocardiographical calculations just prior to discharge. Inadequate repair is determined by precise measurements; therefore, its results are not influenced by provider opinion of the adequacy of the surgical repair. Inadequate repairs as identified by the Technical Performance Score have been shown to have high correlations to mortality. Further work is needed to move the Technical Performance Score into the operating room. Calculating Technical Performance Score during the intraoperative echocardiogram has the potential to decrease the need for reoperations.

Several factors may affect a researcher's choice of a risk adjustment tool. Risk Adjustment for Congenital Heart Surgery, Aristotle Basic Complexity score and Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery scores compares risk of mortality based on surgical procedure. Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery and Aristotle Comprehensive Complexity score add patient variables such as age, prematurity, and preoperative condition to the calculation increasing its discrimination for risk of mortality. However, Aristotle Comprehensive Complexity score adds specific subjective patient factors that influence complexity, potentially affecting generalizability and leading to challenges in comparisons across institutions. Vasoactive Inotrope Score measures risk of mortality on a patient level; therefore, multiple diagnoses and procedures could have similar scores. This can be helpful for research analyzing interventions stratified by severity of illness rather than diagnoses. Vasoactive Inotrope Score could be used to compare institutional experiences. Technical Performance Score also measures at an individual patient level but is based on specific surgical interventions. Mitral valve repair, for example, may be necessary in multiple types of CHD surgical procedures. Technical Performance Score, in conjunction to another mortality risk tool (e.g. Risk Adjustment for Congenital Heart Surgery, Aristotle Basic Complexity score, or Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery), has the potential to determine if suboptimal repair in one type of CHD compared to another type has a higher risk of mortality.

The choice of risk adjustment tools may also be influenced by feasibility. Risk Adjustment for Congenital Heart Surgery stratifies patients into one of five risk categories based on the complexity of surgical procedure. The Risk Adjustment for Congenital Heart Surgery model includes seven additional variables that are easily obtained, such as age, prematurity, gender, and non-cardiac anomalies.[45] Stratification can be determined by clinicians and researchers using the published diagnoses and corresponding Risk Adjustment for Congenital Heart Surgery categories. Aristotle Basic Complexity score can also be determined using the published diagnoses table with the corresponding point system. Calculating an Aristotle Comprehensive Complexity score involves scoring in three components: mortality, morbidity, and surgical technical difficulty.[75] This calculation also requires a subscription to access the scoring tool. The Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery risk model adjusts for 13 components, including primary surgical procedure. Seven of the components are similar to Risk Adjustment for Congenital Heart Surgery; however, the model has six additional variables. The complexity of this tool may be too burdensome for some centers performing congenital heart surgery and therefore, unavailable to researchers. Furthermore, the Society of Thoracic Surgeon-European Association for

Cardio-Thoracic Surgery score is only available to surgeons/institutions that submit data to the Society of Thoracic Surgery. Technical Performance Score requires measurements through routine postoperative echocardiography. The measurements, however, require a capable echocardiographer and therefore may not be available for a retrospective study.

Conclusion

Multiple tools measure risk of mortality following surgery for CHD. These tools vary in their areas of focus: complexity of surgical procedure (Risk Adjustment for Congenital Heart Surgery, Aristotle Basic Complexity score, and Society of Thoracic Surgeon-European Association for Cardio-Thoracic Surgery), postoperative physiologic markers (Vasoactive Inotrope Score), and success of surgical technical performance (Technical Performance Score). Tools to stratify risk of mortality are useful to determine the risk of procedures, but are limited by not including all surgical procedures. This limitation is obviously of particular importance for novel procedures that often have increased risk. On the other hand, while the Vasoactive Inotrope Score has demonstrated high sensitivity and specificity, it needs significant further validation across populations. It has an advantage in that it uses postoperative scores based on physiologic markers and support requirements. These data are more easily calculated in real time and reflect individual patient characteristics. Technical Performance Score is currently used to review and critique technical surgical performance. All Technical Performance Score measurements utilize objective data to determine surgical performance score and have demonstrated excellent discrimination for risk of mortality. In sum, the available tools measure risk of mortality at different points along the continuum of care. Researchers must choose a risk adjustment tool that is feasible given available data and resource constraints, while also making sure that the tool selected aligns with their area of research.

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35. Nathan M, Sadhwani A, Gauvreau K, et al. Association between Technical Performance Scores and neurodevelopmental outcomes after congenital cardiac surgery. J Thorac Cardiovasc Surg 2014;148:232-7.e3.

36. Heinrichs J, Sinzobahamvya N, Arenz C, et al. Surgical management of congenital heart disease: evaluation according to the Aristotle score. European journal of cardio-thoracic surgery : official journal of the European Association for Cardio-thoracic Surgery 2010;37:210-7.

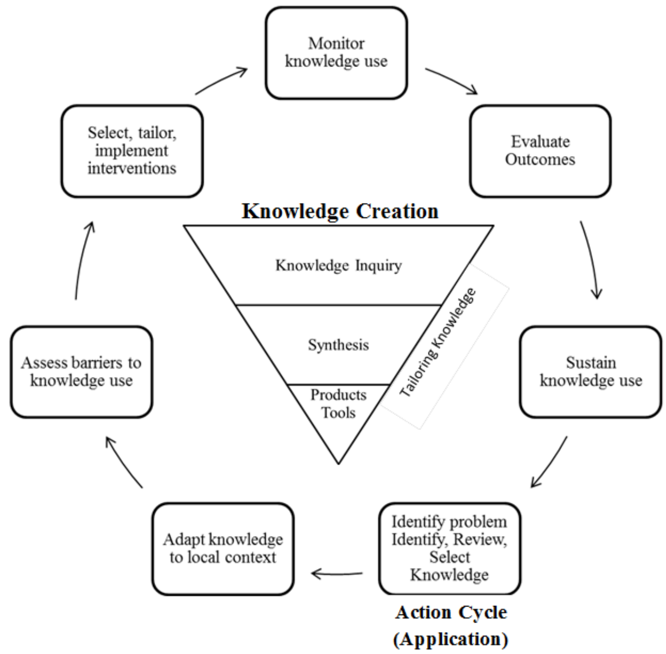

Figure 1. Diagram of Knowledge-to-Action Theoretical Framework

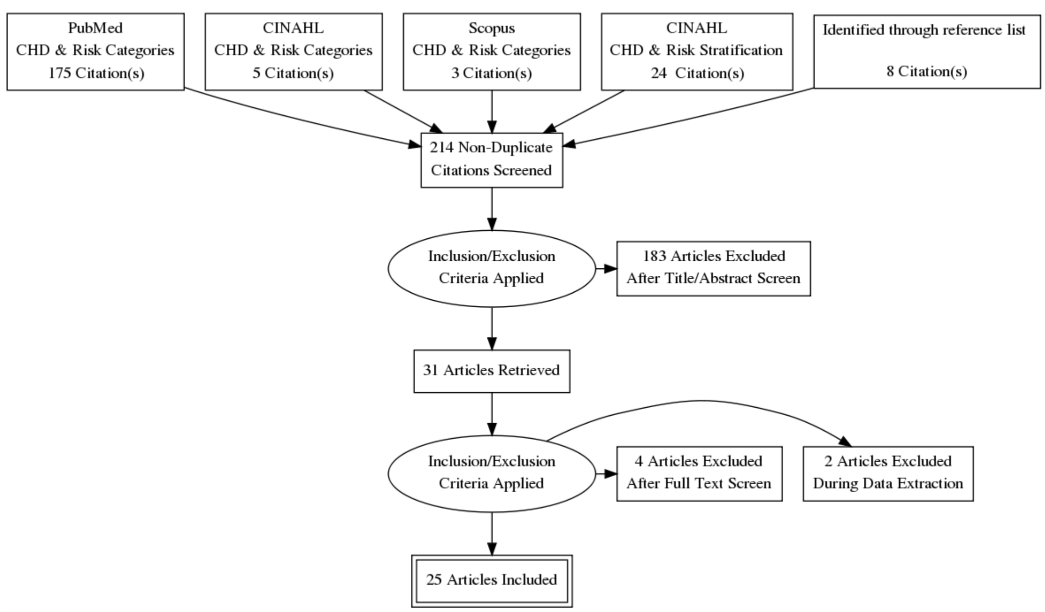

Figure 2. PRISMA Flow diagram of Literature Search Strategy

Table 1
Name of tool: **Risk Adjustment for Cardiac Surgery (RACHS-1)**
Instrument description and scoring: Risk of mortality stratified to one of 6 risk categories based on surgical repair.
Feasibility: Able to easily identify diagnoses present in risk categories. However, not all diagnoses are included e.g. heart transplant or innovative techniques

Author Title	Sample Subjects	Reliability	Validity	Conclusion	Level of Evidence
Jenkins, K. J., Gauvreau, K., Newburger, J. W., Spray, T. L., Moller, J. H., & Iezzoni, L. I. (2002). Consensus-based method for risk adjustment for surgery for congenital heart disease.	4602 Surgical patients in PCCC. 3832 hospital discharge data (3 states). Patients less than 18 years in North America	Not reported but tested against database of actual patient results.	Model tested against actual reported mortality with a c-statistic of .811 and .814 in two datasets.	Variables are easy to collect and are predictive of mortality.	2b Retrospective cohort study based on expert opinion (level 5) but tested on retrospective data.
Boethig, D., Jenkins, K. J., Hecker, H., Thies, W. R., & Breymann, T. (2004). The RACHS-1 risk categories reflect mortality and length of hospital stay in a large German pediatric cardiac surgery population.	2368 procedures that were performed consecutively on 2223 patients under 18 years of age in Germany.	Not reported but tested against database of actual patient results.	Model tested against actual reported mortality with a c-statistic of .755	RACHS-1 classification is applicable to European pediatric populations	2b Retrospective cohort study
Larsen, S. H., Pedersen, J., Jacobsen, J., Johnsen, S. P., Hansen, O. K., & Hjortdal, V. (2005). The RACHS-1 risk categories reflect mortality and length of stay in a Danish population of children operated for congenital heart disease.	1019 surgical heart operations were performed in 889 children aged 15 years or younger in Denmark.	Not reported but tested against database of actual patient results.	Model tested against actual reported mortality with c-statistic of .741	RACHS-1 Classification can be applied to smaller surgical programs	2b Retrospective cohort study
Simsic, J. M., Cuadrado, A., Kirshbom, P. M., & Kanter, K. R. (2006). Risk adjustment for congenital heart surgery (RACHS): is it useful in a single-center series of newborns as a predictor of outcome in a	114 newborns less than 15 days of age in the United States	Not reported but tested against database of actual patient results.	Risk category 4 had a 1.5 increased odds ratio compared to those in risk category 6. Risk category 2 had an increased odds ratio of 6 compared to risk category 3.	Limited use of RACHS-1 in high-risk newborns may be due to confounding variables. Recommend further risk adjustment tool that includes these variables in the model.	2b Retrospective cohort study

Author Title	Sample Subjects	Reliability	Validity	Conclusion	Level of Evidence
high-risk population?					
Nina, R. V., Gama, M. E., Santos, A. M., Nina, V. J., Figueiredo Neto, J. A., Mendes, V. G., . . . Brito, L. M. (2007). Is the RACHS-1 (risk adjustment in congenital heart surgery) a useful tool in our scenario?	145 patients less than 18 years of age in Brazil.	Not reported but tested against prospective collection of actual patient results.	Dataset patients were risk category 1-3 only. None met criteria for risk category 5-6 and those in category 4 were excluded as it was only 1.3% of the sample. Mortality was significantly higher than predicted mortality.	Tool was easy to apply but not applicable to a developing program in a poor, underserved area.	2b Retrospective cohort study
Awori, M. N., & Ogendo, S. W. (2008). Rachs-1 system in risk stratification for congenital heart disease surgery outcome	317 procedures on 313 patients less than 18 years of age in Kenya.	Not reported but tested against retrospective collection of actual patient results.	Dataset patients were risk category 1-4 only. None met criteria for risk category 5-6. Category 4 only contained 2 patients. Mortality was significantly higher than predicted mortality.	Developing countries have low caseloads; therefore, it would take many years to obtain a sufficient sample to test RACHS-1.	2b Retrospective cohort study
Miyata, H., Murakami, A., Tomotaki, A., Takaoka, T., Konuma, T., Matsumura, G., . . . Takamoto, S. (2014). Predictors of 90-day mortality after congenital heart surgery: the first report of risk models from a Japanese database.	8923 **c**ongenital heart operations performed at 69 sites in Japan.	Not reported but tested against database of actual patient results.	C-statistics were calculated for 30-day, 90-day, and 90-day and in-hospital mortalities. Results were .79, .81, and .84 respectively in a multivariate model. RACHS-1 only was c-statistic .73-.77. .	RACHS-1 demonstrated high discrimination for predicting mortality.	2b Retrospective cohort study

Table 2

Name of tool: **Aristotle Basic Complexity Score (ABC), Aristotle Comprehensive Score (ACC**)
Instrument description and scoring: Procedure-adjusted complexity. Score comprised of 3 components: mortality potential, morbidity potential, and technical difficulty
Feasibility: Classifications are available for 131 surgical procedures. It requires identification of primary surgical procedure.

Author Title	Sample Subjects	Reliability	Validity	Conclusion	Level of Evidence
O'Brien, S. M., Jacobs, J. P., Clarke, D. R., Maruszewski, B., Jacobs, M. L., Walters, H. L., 3rd, . . . Lacour-Gayet, F. G. (2007). Accuracy of the aristotle basic complexity score for classifying the mortality and morbidity potential of congenital heart surgery operations.	European Association of Cardiothoracic Surgery (EACTS) congenital database (17,838 operations, 56 centers) and the Society of Thoracic Surgeons (STS) congenital database (18,024 operations, 32 centers) in North America.	Not reported but tested against database of actual patient results.	Positive correlation between ABC score and observed mortality with c-statistic of.70.	Discriminates well between low and high risk procedures.	2b Retrospective cohort study
Sinzobahamvya, N., Photiadis, J., Kumpikaite, D., Fink, C., Blaschczok, H. C., Brecher, A. M., & Asfour, B. (2006). Comprehensive Aristotle score: implications for the Norwood procedure. *The Annals Of Thoracic Surgery, 81*(5), 1794-1800	39 consecutive infants 4-275 days of age undergoing Norwood Stage I palliation for single ventricle physiology in a single center in Germany.	Higher ACC score indicative of higher risk of mortality. Mortality was 58.8% in patients with scores of at least 20 compared to 9.1 when score was less than 20.	Calculation of survival of those with a ACC 20 or greater than those with an ACC of less than 20 with p <.001.	ACC demonstrated correlation with early death after Norwood stage I palliation. ACC demonstrated the effect of variables related to mortality such as surgery in infants older than 14 days and preoperative low cardiac output states.	2b Retrospective cohort study
Arenz, C., Asfour, B., Hraska, V., Photiadis, J., Haun, C., Schindler, E., & Sinzobahamvya, N. (2011). Congenital heart surgery: surgical performance according to the Aristotle complexity score.	1828 primary procedures in patients less than 18 years of age collected prospectively in Germany. Both ABC and ACC were calculated.	ACC with Pearson coefficient r = 1; therefore perfect correlation.	Both ABC, ACC scores representative of actual mortality.	ACC more complex to calculate leading ABC likely to be used more frequently. Authors interested in trend of ABC, ACC as measure of surgical performance.	2b Prospective cohort study but no intervention
Bojan, M., Gerelli, S., Gioanni, S., Pouard, P., & Vouhe, P. (2011). The Aristotle Comprehensive Complexity score predicts mortality and morbidity after congenital heart surgery	1368 patients less than 18 years of age in France. Both ABC and ACC were calculated.	ACC score was strongly related to 30-day mortality. Regression coefficient, 0.32 ± 0.04; p < 0.0001; and R^2 = 0.24 showed good overall performance.	Strongly discriminated mortality with c-statistic of .864	ACC can predict 30-day mortality. Acceptable tool for adjustment of complexity.	2b Retrospective cohort study

Table 3

Name of tool: Originally **STS–EACTS Congenital Heart Surgery Mortality Score** then shortened to **STAT Mortality Categories**
Instrument description and scoring: Empirical registry data were used to group surgical procedures into five homogenous risk categories based on surgical procedure with a scale from 0.1-5.0.
Feasibility: Score is available for over 148 types of operative procedures.

Author Title	Sample Subjects	Reliability	Validity	Conclusion	Level of Evidence
O'Brien, S. M., Clarke, D. R., Jacobs, J. P., Jacobs, M. L., Lacour-Gayet, F. G., Pizarro, C., . . . Edwards, F. H. (2009). An empirically based tool for analyzing mortality associated with congenital heart surgery	43,934 operations from 57 centers in the STS database and 33,360 operations in patients less than 18 years of age from 91 centers in the EACTS database for a total of 77,294 operations. Databases included North America and Europe.	Not reported but tested against database of actual patient results.	Discriminated risk of mortality C-statistic.787 compared to RACHS-1 of .745 and ABC score .678	Scores developed through empiric data rather than determination by experts. Scores can used to compare institutions.	2b Retrospective cohort study
Jacobs, J. P., O'Brien, S. M., Pasquali, S. K., Jacobs, M. L., Lacour-Gayet, F. G., Tchervenkov, C. I., . . . Mavroudis, C. (2012). Variation in outcomes for risk-stratified pediatric cardiac surgical operations: an analysis of the STS Congenital Heart Surgery Database	58,506 index operations in patients less than 18 years of age at 73 centers in North America.	Funnel plot analysis demonstrate most centers within 95% of the limits of prediction.		Risk grouping allows for more cases of infrequent but similar risk of mortality cases for analysis.	2b Retrospective cohort study

Table 4

Name of tool: **Vasoactive-inotrope score (VIS)**
Instrument description and scoring: Score determine by cumulative dose of all infusing inotropic agents. Scores calculated to give each agent equal weight when added together. Scores are then divided into one of five group assignments.
Feasibility: Score can be calculated easily at the bedside as often as clinically desired.

Author Title	Sample Subjects	Reliability	Validity	Conclusion	Level of Evidence
Gaies, M. G., Gurney, J. G., Yen, A. H., Napoli, M. L., Gajarski, R. J., Ohye, R. G., . . . Hirsch, J. C. (2010). Vasoactive-inotropic score as a predictor of morbidity and mortality in infants after cardiopulmonary bypass.	Retrospective chart review of 174 infants ages birth to six months of age.	The VIS score of 4&5 had a sensitivity of 0.71 and specificity of 0.80 for poor outcome. High maximum VIS strongly associated with poor outcome with adjusted odds ratio of 8.1, prolonged time to first extubation (OR 5.5) and prolonged LOS (OR2.4).	Due to low morality c-statistic was not calculated for mortality. C-statistic for all time points for prolonged intubation ranged from .88-.92.	High VIS a surrogate marker for severity of illness. This information can be used to comparison across centers and in clinical research.	2b Retrospective cohort study
Davidson, J., Tong, S., Hancock, H., Hauck, A., da Cruz, E., & Kaufman, J. (2012). Prospective validation of the vasoactive-inotropic score and correlation to short-term outcomes in neonates and infants after cardiothoracic surgery	Prospective observational study of 70 infants ages ≤90 days of age in the United States. VIS calculated at 24 hours, 48 hours, max 48 hours and 72 hours following surgery.	Association with poor outcome had an odds ratio of 6 and a *p* value of 0.76. However, only nine patients met criteria for poor outcome in this sample.	VIS performed well across all time points with c-statistic of .90, .93, .88, and .92 respectively.	More predictive of ICU and hospital length of stay. 48 hours score predictive of short term outcome. Small sample size and proportion of poor outcomes unable to assess for prediction of mortality.	2b Prospective cohort study but no interventions
Kumar, M., Sharma, R., Sethi, S. K., Bazaz, S., Sharma, P., Bhan, A., & Kher, V. (2014). Vasoactive Inotrope Score as a tool for clinical care in children post cardiac surgery	Retrospective review of 208 patients with mean age of 66.94 months in India.	None reported.	Authors stated high VIS scores at 48 hours was associated with increased need for ventilator support but no statistics were published.	Increased VIS score in the postoperative recovery associated with increased morbidity and mortality. This information may influence postoperative intervention and decision-making.	2b Retrospective cohort study

Table 5

Name of tool: **Technical Performance Scores (TPS)**
Instrument description and scoring: TPS was assigned according to the echocardiographic findings and clinical status at discharge. The procedures were subdivided into components, and each component was scored as class 1 (optimal), class 2 (adequate), or class 3 (inadequate) using specific echocardiographic criteria
Feasibility: Requires capable echocardiographer to obtain required measurements.

Author Title	Sample Subjects	Reliability	Validity	Conclusion	Level of Evidence
Karamichalis, J. M., Colan, S. D., Nathan, M., Pigula, F. A., Baird, C., Marx, G., . . . del Nido, P. J. (2012). Technical performance scores in congenital cardiac operations: a quality assessment initiative.	185 patients less than 18 years of age in the United States.	Not reported but tested against database of actual patient results.	Univariate analysis demonstrated and association between TPS and mortality with a *p* value of 0.001.	Feasibility established for a new technical performance scoring system. Can be used to determine optimal result and comparison of surgical performance.	2b Retrospective cohort study
Nathan, M., Karamichalis, J. M., Liu, H., Emani, S., Baird, C., Pigula, F., . . . Del Nido, P. (2012). Surgical technical performance scores are predictors of late mortality and unplanned reinterventions in infants after cardiac surgery.	166 infants age 6 months and younger in United States. Outcomes followed for one year. Seven patients died prior to one year.	None reported	Univariate analysis association with mortality ($p < .001$) and reintervention ($p = .04$). Inadequate TPS score was associated with late mortality ($p < .001$; odds ratio of 7.2).	Supports need for early assessment of TPS and need for early reintervention.	2b Retrospective cohort study
Nathan, M., Pigula, F. A., Liu, H., Gauvreau, K., Colan, S. D., Fynn-Thompson, F., . . . Del Nido, P. J. (2013). Inadequate technical performance scores are associated with late mortality and late reintervention	Retrospective chart review of 725 patients (52 were greater than 18 years of age). 679 survived to discharge. 409 followed for greater than 4 years.	Not reported but tested against database of actual patient results.	TPS, age, RACHS-1, STAT are significant for mortality with a $p < .001$.	Support the use of TPS as an individual, institution and across institution benchmark for quality.	2b Retrospective cohort study
Nathan, M., Karamichalis, J., Liu, H., Gauvreau, K., Colan, S., Saia, M., . . . del	1926 procedures in 1714 patients age 0-68 years (211, 11% were adults).	Class 3 or inadequate TPS had an odds ratio of 16.9 ($p < .001$) of mortality.	Univariate analysis TPS, age, RACHS-1, prematurity, and presence	Single center validation and needs to be reproduced over multiple centers.	2b Retrospective cohort study

Author Title	Sample Subjects	Reliability	Validity	Conclusion	Level of Evidence
Nido, P. J. (2014). Technical Performance Scores are strongly associated with early mortality, postoperative adverse events, and intensive care unit length of stay-analysis of consecutive discharges for 2 years			of non-cardiac or chromosomal anomalies were significantly associate with mortality (*p* <.001). On multivariate analysis TPs strongly associated with mortality.	Authors disclose current multicenter study in progress.	

Table 6: **Studies Comparing Complexity Instruments**

Author Title	Sample Subjects	Reliability	Validity	Conclusion	Level of Evidence
Al-Radi, O. O., Harrell, F. E., Jr., Caldarone, C. A., McCrindle, B. W., Jacobs, J. P., Williams, M. G., . . . Williams, W. G. (2007). Case complexity scores in congenital heart surgery: a comparative study of the Aristotle Basic Complexity score and the Risk Adjustment in Congenital Heart Surgery (RACHS-1) system.	13,675 in retrospective database of children less than 18 years of age in a single institution in Canada. 11, 438 cases could be assigned both **RACHS-1** and **ABC**.	RACHS-1was more predictive of mortality with likelihood ratio x^2 = 13.4, $p < .001$ compared the ABC with likelihood ratio x^2 162, p = .009.	C-statistic for RACHS-1 was .763 compared to ABC .737.	Both RACHS-1 and ABC have strong prediction of in-hospital mortality. RACHS-1 demonstrated higher predictive ability.	2b Retrospective cohort study
Jacobs, J. P., Jacobs, M. L., Lacour-Gayet, F. G., Jenkins, K. J., Gauvreau, K., Bacha, E., . . . Mavroudis, C. (2009). Stratification of complexity improves the utility and accuracy of outcomes analysis in a Multi-Institutional Congenital Heart Surgery Database: Application of the Risk Adjustment in	Database of 45,635 cases in children < 18 years of age from 47 centers in North America. Compared **RACHS-1** and **ABC**.	Not reported but tested against database of actual patient results	C-statistic for ABC .70. It increased to .74 when clinical factors were incorporated into the model. C-statistic for RACHS-1 was .743 and increased to .814 was clinical factors added to model.	ABC able to be assigned to more cases whereas RACHS-1 has better discriminates higher complexity.	2b Retrospective cohort study

Author Title	Sample Subjects	Reliability	Validity	Conclusion	Level of Evidence
Congenital Heart Surgery (RACHS-1) and Aristotle Systems in the Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database.					
Vijarnsorn, C., Laohaprasitiporn, D., Durongpisitkul, K., Chantong, P., Soongswang, J., Cheungsomprasong, P., . . . Pooliam, J. (2011). Surveillance of pediatric cardiac surgical outcome using risk stratifications at a tertiary care center in Thailand.	Retrospective analysis of database of 230 children ≤ 15 years of age in single center in Thailand. Compared RACHS-1, ABC, and STS-EACTS.	Not reported but tested against database of actual patient results	The c-statistic results were as follows: RACHS-1 .78, ABC .74, STS-EACTS .67.	Small sample size but all three tools able to be used to assess risk of mortality in medium size Thai hospital.	2b Retrospective cohort study
Vasdev, S., Chauhan, S., Malik, M., Talwar, S., Velayoudham, D., & Kiran, U. (2013). Congenital heart surgery outcome analysis: Indian experience	Prospective analysis of 1312 patients < 18 years of age in India. Comparison of RACHS-1, ABC, and STS-EACTS mortality categories.	Correlation of ABC (*r* = .0.9529) and RACHS-1 (*r* = .9866) and STS-EACTS (*r* = .8411).	RACHS-1 had a c-statistic of .7654, ABC .6676, and STS-EACTS mortality categories .75556.	RACHS-1 was best able to predict mortality. Sample did not contain any RACHS-1 5, 6 or STS-EACTS mortality category 5.	2b Prospective cohort study but no interventions
Joshi, S. S., Anthony, G., Manasa, D., Ashwini, T., Jagadeesh, A. M., Borde, D. P., . . . Manjunath, C. N. (2014). Predicting mortality after congenital heart surgeries: evaluation of the Aristotle and Risk Adjustment in Congenital Heart Surgery-1 risk prediction scoring systems: a retrospective single center analysis of 1150 patients.	Retrospective single center study of 1150 patients less than 18 years of age in tertiary hospital in India. Compared results of RACHS-1, ABC, ACC.	Not reported but tested against database of actual patient results	ACC with c-statistic of .704. ABC .677, and RACHS-1 .607.	Aristotle comprehensive complexity had highest c-statistic indicating best predictability; however, observed mortality of 7.91% much higher than other studies. Ability for accurate prediction of mortality in developing country is difficult due to multiple confounding variables. These include age, late diagnoses, malnutrition, and high percentage of pulmonary hypertension among others.	2b Retrospective cohort study

Cardiac Arrest Associated with Endotracheal Suctioning Following Surgery for Congenital Heart Disease

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Abstract

Critically ill pediatric patients with congenital heart disease, recovering after cardiac surgery with endotracheal tubes routinely receive endotracheal suctioning to clear secretions and assure tube patency. However, suctioning may result in cardiac arrest in some patients. Study objectives were to 1) determine the characteristics of pediatric congenital heart surgery patients who experienced cardiac arrest during endotracheal suctioning compared to: a) those whose cardiac arrest was not during suctioning and b) those who experienced suctioning without cardiac arrest, 2) identify the changes in physiologic parameters in intubated pediatric CHD patients 30 minutes prior to suctioning and/or arrest event, 3) examine the events preceding cardiac arrest to determine any precipitating or exacerbating factors (e.g. procedures, patient care interventions, or pain/agitation). The conceptual framework that supported this study was the effect of cardiopulmonary interaction in children with CHD and the influence of endotracheal suctioning on the interaction. The sample included 135 events of pediatric congenital heart surgery patients who experienced cardiac arrest during endotracheal suctioning (n=18) compared to those whose cardiac arrest was not during suctioning (n=81) and those who experienced suctioning without cardiac arrest (n=36). Initial analysis compared all those who experienced arrest to those who did not experience arrest. Subsequently, three groups were compared as follows: pediatric congenital heart surgery patients who a) experienced cardiac arrest during endotracheal suctioning, b) those whose cardiac arrest was not during suctioning, and c) those who experienced suctioning without cardiac arrest. Multinomial logistic regression was conducted including all variables with a p value <0.20 from bivariate analysis with cardiac arrest during endotracheal suctioning as the reference category. The final model demonstrated

heart rate, chemical paralysis at the time of suctioning, postoperative intensive care unit length of stay, and survival to discharge were significant variables. Endotracheal suctioning is a routine procedure in pediatric intensive care units throughout the world; consequently, establishing practice guidelines to avert cardiac arrest during endotracheal suctioning is critical to improving patient outcomes. This study revealed those who experienced cardiac arrest underwent a greater than 20% change in heart rate within 30 minutes prior to event, indicating a possible signal of increased risk. Further, those patients who experienced cardiac arrest were not chemically paralyzed, emphasizing a particular period of vulnerability compared to suctioning while chemically paralyzed; had a longer postoperative ICU length of stay, affecting resource utilization; and had higher mortality than those who experienced suctioning but did not experience cardiac arrest.

Arrest Associated with Endotracheal Suctioning Following Surgery for Congenital Heart Disease.

Among the necessary, routine procedures performed on children after surgery for congenital heart defects (CHD) is endotracheal suctioning, an intervention with the potential to precipitate cardiac arrests (Morrow & Argent, 2008; Ofori-Amanfo & Cheifetz, 2013). Cardiac arrest following pediatric surgery for CHD contributes to morbidity and mortality in a variety of ways, including compromised brain function and increased length of stay (Bloom, Wright, Morris, Campbell, & Krawiecki, 1997; De Oliveira et al., 2004; Kalloghlian, Matthews, & Khan, 1998; Lowry et al., 2013; Parra et al., 2000; Rhodes et al., 1999; Rossano et al., 2014). Because of the serious risk for cardiac arrest following pediatric CHD surgery, this study sought to determine whether specific hemodynamic changes predicted cardiac arrest during endotracheal suctioning in the postoperative child with CHD. New data capture technology (Tracking, Trajectory, and Trigger [T3], Etiometry Inc.) enabled the research team to collect hemodynamic data automatically every 5 seconds to assess for trends in a more detailed manner than previously available (Hagland, 2013). The outcomes of this study can provide a basis for developing guidelines on optimal suctioning strategies with potential to prevent cardiac arrest. This retrospective study examined patient, clinical, and system-level factors present following CHD surgery in those who experienced cardiac arrest during endotracheal suctioning compared to those whose cardiac arrest did not occur during suctioning, and those who experienced suctioning but not cardiac arrest.

Current suctioning recommendations for children with CHD have been derived from adult studies or small general pediatric studies (Gillies & Spence, 2011; Morrow & Argent, 2008; Pritchard, Flenady, & Woodgate, 2001; Taylor, Hawley, Flenady, & Woodgate, 2011; Walsh, Hood, & Merritt, 2011). However, among children with CHD, the risk of cardiac arrest is substantially higher than in children without CHD. Seven out of every 1,000 hospitalizations of children with CHD are complicated by cardiac arrest compared to 0.54/1,000 hospitalizations of children without CHD (Lowry et al., 2013). Cardiac arrest has been grouped as hypotension (30%) followed by arrhythmia (29%), respiratory failure (12%), metabolic (8%), but the causes of 21% of arrests are identified only as “other” (Parra et al., 2000).

The normal human circulatory system has two distinct systems with equal and balanced blood flow: pulmonary circulation and systemic circulation. These two systems operate in series, where deoxygenated blood returning from the body is delivered to the pulmonary circulation for oxygenation, then continues to the systemic circulation for distribution of the newly oxygenated blood to the body (Barnea, Austin, Richman, &

Santamore, 1994). In CHD these two systems are often pathologically unseparated; therefore, balancing the two blood flows is a focus of clinical care (Barnea et al., 1994; Dhillon, Yu, Zhang, Cai, & Li, 2015; Francis, Willson, Thorne, Davies, & Coats, 1999). Imbalance can result in cardiac arrest, as high pulmonary blood flow (Qp) can decrease systemic blood flow (Qs), leading to low cardiac output and consequently low blood pressure; conversely, too much shunting of blood away from the lungs (Qs higher than Qp) can cause hypoxemia (Bronicki & Chang, 2011; Ofori-Amanfo & Cheifetz, 2013).

Endotracheal suctioning can have a significant hemodynamic effect on children with CHD, altering the Qp: Qs ratio and resulting in cardiac arrest. Postoperative care frequently requires mechanical ventilation via an endotracheal tube. Common practice includes intermittent suctioning of the tube to clear secretions and maintain patency. Suctioning frequency is often determined by clinician assessment of need or unit practice standards. The process of interrupting ventilation for endotracheal tube suctioning results in acute changes in blood oxygen and carbon dioxide levels, and pH (Bronicki & Chang, 2011; Morrow & Argent, 2008; Morrow, Futter, & Argent, 2006; Morrow, Futter, & Argent, 2004; Ofori-Amanfo & Cheifetz, 2013). These changes can have a catastrophic effect on some children with CHD because the changes produce a potentially deleterious effect on cardiopulmonary interaction related to residual structural or physiological cardiac disease (Kocis & Meliones, 2000). Oxygen decreases pulmonary vascular resistance; however, in children with right-to-left shunts, oxygen can decrease oxygen delivery. It can also increase systemic vascular resistance, thus increasing left ventricular afterload, which decreases cardiac output. A rise in carbon dioxide and the resultant decrease in pH increases pulmonary vascular resistance and decreases systemic vascular resistance. Decreased carbon dioxide and increased pH consequently decrease pulmonary vascular resistance and increase systemic vascular resistance. Both states can decrease cardiac output, altering afterload and affecting ventricular function (Kocis & Meliones, 2000).

Current literature on endotracheal suctioning concentrates on pain as a result of the practice, efficacy of suctioning technique, and the effect on specific patient populations, such as preterm infants and children with traumatic brain injury (Cone, Pickler, Grap, McGrath, & Wiley, 2013; Cury, Martinez, & Carlotti, 2013; Evans, Syddall, Butt, & Kinney, 2014; Gillies & Spence, 2011; Kaiser, Gauss, & Williams, 2008, 2011; Karpe, Misiolek, Daszkiewicz, & Misiolek, 2013; Limperopoulos et al., 2008; Peyrovi, Alinejad-Naeini, Mohagheghi, & Mehran, 2014; Pirr, Lange, Hartmann, Bohnhorst, & Peter, 2013; Pritchard et al., 2001; Rieger, Kuhle, Ipsiroglu, Heinzl, & Popow, 2005; Sonmez Duzkaya & Kuguoglu, 2015; Spence, Gillies, & Waterworth, 2003; Taylor et al., 2011; Tume, Baines, & Lisboa, 2011; Walsh et al., 2011). Literature on cardiac arrest in children with CHD primarily concentrates on patient characteristics, nursing perceptions, incidence, resuscitation procedures, and patient outcomes (Bloom et al., 1997; Chrysostomou et al., 2013; Collins & Vawdrey, 2012; Duncan et al., 1998; Ferguson, Durward, & Tibby, 2012; Flick et al., 2007; Jindal, Jayashree, & Singhi, 2011; Kalloghlian et al., 1998; Lowry et al., 2013; Ma, Gauvreau, Allan, Mayer, & Jenkins, 2007; Mahle, Spray, Gaynor, & Clark, 2001; Odegard et al., 2007; Parra et al., 2000; Peddy et al., 2007; Rhodes et al., 1999; Rossano et al., 2014; Timerman et al., 2001). In particular, the literature on cardiopulmonary interactions in children with CHD does not examine the effect of endotracheal suctioning (Bronicki & Anas, 2009; Bronicki &

Chang, 2011; Kocis & Meliones, 2000). Many studies in children with CHD are retrospective and identified characteristics such as age, weight, and diagnoses that were associated with increased prevalence of cardiac arrest from all causes. Literature in the area also includes instructive manuscripts on resuscitation considerations specific to patients with CHD; however, these reports focus on resuscitation procedures rather than prevention of arrest (Parra et al., 2000; Peddy et al., 2007).

Patient survival, neurological impact, and other sequalae of cardiac arrest have also been studied. The data analyses generally began at the time of arrest and examined the interventions and outcomes following cardiac arrest. In contrast, this study examined data prior to arrest to identify predictive factors. Specifically, the objectives were to: 1) determine the characteristics of pediatric congenital heart surgery patients who experienced cardiac arrest during endotracheal suctioning compared to those whose cardiac arrest was not during suctioning and those who experienced suctioning without cardiac arrest; 2) identify the changes in physiologic parameters in intubated pediatric CHD patients 30 minutes prior to suctioning and/or arrest events; 3) examine the events preceding cardiac arrest to determine any precipitating or exacerbating factors (e.g. procedures, patient care interventions, or pain/agitation). The results of this study will also be significant to clinicians caring for critically ill children without CHD. Due to their smaller size and ongoing growth and development, critically ill children are at increased risk for adverse alterations in cardiopulmonary interaction, which may result in cardiac arrest (Bronicki & Anas, 2009; Monnet, Teboul, & Richard, 2007).

Methods

The conceptual framework that supported this study was the effect of cardiopulmonary interaction in children with CHD and the influence of endotracheal suctioning on the interaction (*Figure 1*).

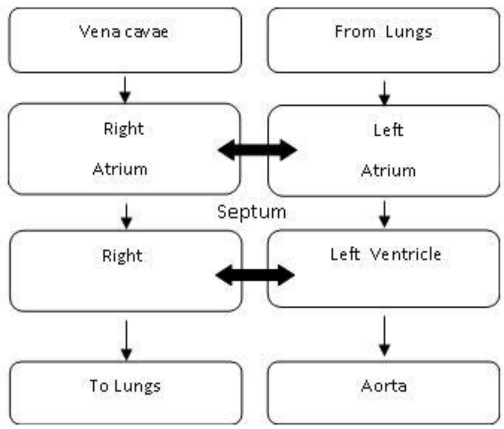

Figure 1.Cardiopulmonary interaction

Normal cardiopulmonary function involves the interaction of pressures and flow both inside and outside of the heart (Bronicki & Anas, 2009). Ventricular filling determines the volume of blood flow to both the pulmonary and systemic circulations. Adequate ventricular filling is needed to ensure adequate oxygen delivery to the body. The ventricular volume is the result of ventricular diastolic transmural pressure; that is, the ventricular diastolic pressure minus the surrounding intrathoracic pressure (Bronicki & Chang, 2011). In CHD, there are many components that affect pressure and flow that can result in a decrease in ventricular filling. For instance, pulmonary hypertension is an increased pressure impeding the blood flow out of the right ventricle as well as moving the intraventricular septum into the left ventricle, affecting its volume (Kocis & Meliones, 2000). Children with dilation, hypertrophy or dysfunction of either ventricle have pressure changes that alter the position of the septum, which may decrease ventricular filling (Kocis & Meliones, 2000). The pressure changes can result in shunting of blood via septal openings that may be present in CHD. Acute changes in the degree of shunting can decrease blood flow to the lungs, resulting in hypoxemia, or to the body, resulting in low cardiac output (Bronicki & Anas, 2009; Bronicki & Chang, 2011; Kocis & Meliones, 2000; Ofori-Amanfo & Cheifetz, 2013). Furthermore, the influence of pulmonary physiology on blood oxygenation and carbon dioxide levels, and pH also produces a significant effect on the cardiopulmonary interaction. Endotracheal suctioning interrupts mechanical ventilation, decreasing oxygen delivery and carbon dioxide removal, consequently altering pH. Additionally, the suction removes oxygen along with secretions. Cardiopulmonary interaction can be negatively affected during postoperative care of children with CHD.

Five years of cardiac arrest data were analyzed to identify sequences predicative of cardiac arrest and associated with endotracheal tube suctioning. Data were extracted from four sources: a) the Boston Children's Hospital's pediatric cardiac intensive care unit (PCICU) cardiac arrest database, b) the Boston Children's Hospital's cardiac surgery patient database, c) the T^3 analytics platform, which provided hemodynamic monitoring data captured every five seconds and d) electronic medical records (EMRs). The data were merged to examine each cardiac arrest event, including hemodynamic monitoring data, demographic data, surgical details, and exacerbating events. Patients were divided into three groups: those in whom cardiac arrest occurred during or immediately following endotracheal suctioning (within 10 minutes), those in whom cardiac arrest was not related to suctioning, and those who experienced suctioning without cardiac arrest.

Data from children admitted to the Boston Children's Hospital's PCICU postoperatively from CHD surgery were included in the study data set. CHD is a chronic disease often requiring multiple interventions throughout childhood, thus necessitating consideration of all pediatric age groups. Children with a ventricular assist device or extracorporeal membrane oxygenation were excluded as those devices regulate cardiac output. Children with CHD are admitted directly to the intensive care unit from the operating room. Those who experienced cardiac arrest within the first hour following admission reflected intraoperative circumstances and consequently, had not demonstrated a period of postoperative stability. Therefore, children who experienced cardiac arrest within one hour of admission were excluded. Further inclusion and exclusion criteria are reported in Table 1.

Table 1. Inclusion and exclusion criteria

Inclusion	**Exclusion**
Age < 18 years	Ventricular assist device
Postoperative CHD surgery	Extracorporeal membrane oxygenation (ECMO)
Endotracheal intubation	Cardiac arrest within first hour of PCICU admission

Aim 1. Determine the characteristics of pediatric congenital heart surgery patients who experienced cardiac arrest during endotracheal suctioning compared to those whose cardiac arrest was not during suctioning and those who experienced suctioning without cardiac arrest. Factors obtained for analysis included patient demographics, clinical, and system-level factors (Table 2). The *objective* of this aim was to describe characteristics of patients who experienced cardiac arrest versus those who did not, and among the former group, determine which patient and system-level characteristics are associated with increased risk of cardiac arrest related to endotracheal suctioning. Characteristics included demographic data: age, gender, race, ethnicity, weight, term or premature birth,

insurance type /quantity, and home zip code/country. System factors included pre -and postoperative intensive care unit length of stay, length of cardiopulmonary bypass time, Society of Thoracic Surgeons (STAT) score, inotrope score at time of arrest, use of chemical paralysis, premedication with endotracheal lidocaine prior to suctioning, procedural premedication with narcotics (morphine, fentanyl) and/or anxiolytics (midazolam), and final discharge status. Descriptive statistics (median, range, percentages and frequencies) were calculated and used to compare the arrest group to the non-arrest group. Next, descriptive statistics were calculated for the pediatric congenital heart surgery patients who experienced cardiac arrest during endotracheal suctioning and compared to a) those whose cardiac arrest was not during suctioning and b) those that experienced suctioning without cardiac arrest. Data were checked for normality using the Kolmogorov-Smirnov test. Normal distribution was not present; therefore, the Kruskal-Wallis test was used to compare the continuous variables, and the chi-square test was used to compare the categorical variables for the three groups. STAT category was dichotomized into STAT 1-4, and STAT 4-5. Race was dichotomized into white and non-white. Multinomial logistic regression was performed including all variables with $p<0.20$ in the bivariate analysis in the initial model.

Table 2. Study Variables

Patient Factors	**System Factors**	**Clinical Factors**
Age at time of surgery	Cardiopulmonary bypass time	Heart Rate
Gender	Use of chemical paralysis	Systolic, diastolic, mean blood pressure
Race	Preprocedure premedication	Central Venous Pressure
Weight	Inotrope score	Right Atrial Pressure
History of Prematurity	Precipitating Events if documented	Left Atrial Pressure
Insurance type/quantity	Preoperative ICU Length of Stay	Pulmonary Artery Pressure
Home zip code/country	Postoperative ICU Length of Stay	Near-infrared spectroscopy
STAT Category		Pulse Oximetry oxygen saturation
Non-CHD congenital anomalies		
Survival to hospital discharge		

Aim 2. Identify the changes in physiologic parameters in intubated pediatric CHD patients 30 minutes prior to cardiac arrest associated with suctioning compared to physiologic parameters 30 minutes prior to cardiac arrest not associated with suctioning and suctioning not associated with cardiac arrest. Data were examined to determine differences in the hemodynamic monitoring trends in pediatric congenital heart surgery patients who experienced cardiac arrest compared to those who did not; then, the characteristics of pediatric congenital heart surgery patients who experienced cardiac arrest associated with endotracheal suctioning were compared to characteristics of those whose cardiac arrest was not associated with suctioning (Figure 2).

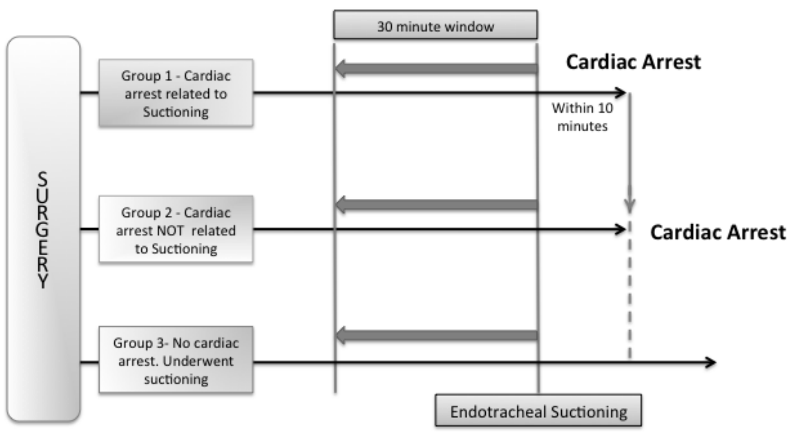

Figure 2. Data Extraction

Hemodynamic monitoring parameters included heart rate, systolic blood pressure, mean arterial pressure, diastolic pressure, central venous pressure, right atrial pressure, pulmonary artery pressure, left atrial pressure, oxygen saturation reported by near infrared spectroscopy (NIRS), and oxygen saturation reported by pulse oximetry. The time of cardiac arrest associated with suctioning was determined from the PCICU cardiac arrest database and the time of suctioning not associated with cardiac arrest was determined from the EMR. Those who experienced suctioning and did not experience cardiac arrest were identified from the CSANDS database and case-control matched to patients who experienced cardiac arrest associated with endotracheal suctioning based on STAT category, age, gender, and cardiopulmonary bypass time. The time of suctioning was extracted from the EMR. This time was recorded as HH:MM in a 24-hour clock. An increase or decrease of 20% in a physiologic parameter was considered hemodynamically significant. This cutoff has been used in other studies to exclude non-pathologic variability (Delaney, Moltedo, Dziura, Kopf, & Snyder, 2006). To determine the timing of hemodynamic changes, the time in minutes of an increase or decrease of 20% in a physiologic parameter prior to endotracheal suctioning was calculated (Figure 3).

Descriptive statistics were calculated comparing the arrest group to the non-arrest group. Next descriptive statistics were calculated for the pediatric congenital heart surgery patients who experienced cardiac arrest associated with endotracheal suctioning and compared to those whose cardiac arrest was not associated with suctioning and those who experienced suctioning without cardiac arrest. Data were checked for normality using the Kolmogorov-Smirnov test. Normal distribution was not present; therefore, the Kruskal-Wallis test was used to compare the continuous variables and chi-square test was used to compare the categorical variables for the three groups. Multinomial logistic regression was performed including all variables with $p<0.20$ from the bivariate analysis in the initial model.

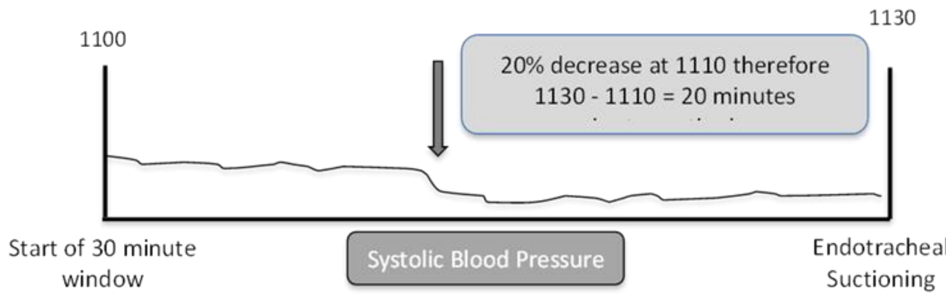

Figure 3. Time Calculation

Aim 3.Examine the events preceding cardiac arrest to determine the incidence of precipitating or exacerbating factors (e.g. procedures, patient care interventions, or pain/agitation) preceding cardiac arrest. Precipitating factors were collected from the EMR (Table 3) to describe prevalence of events in this population.

Table 3. Precipitating/Exacerbating Factors

Types
Painful procedure (IV line/tube insertion, IV line/tube removal)
Agitation/crying
Lifting of chemical paralysis

Results

There were 135 cardiac arrest and/or suctioning events among the three groups: 18 pediatric congenital heart surgery patients who experienced cardiac arrest associated with endotracheal suctioning, 81 patients whose cardiac arrest was not associated with suctioning and 36 patients who experienced suctioning without cardiac arrest.

Aim 1: Demographic data were obtained and differences were determined in the characteristics of patients who experienced cardiac arrest compared to those who did not. Prematurity was over five times more prevalent in the arrest group than in the group that did not experience cardiac arrest (p =0.038). The arrest group had twice the prevalence of STAT 1-3 (p =0.074), indicating lower risk of mortality. Postoperative ICU length of stay in the arrest group was longer with a median of 29.3 days compared to 9.3 days for the non-arrest group (p <0.001). Inotrope score was statistically significantly different with a median of 5 in the non-arrest group compared to 10 in the cardiac arrest group (*p* <0.001). Endotracheal lidocaine was utilized in 13.9% of the non-arrest group but only 3% of the cardiac arrest group (*p* <0.001). Procedural sedation prior to suctioning was given in 25% of the non-arrest group and 7.1% of the cardiac arrest group (*p* <0.001).

Aim 2: Hemodynamic data were obtained and differences were determined in the characteristics of patients who experienced cardiac arrest compared to those who did not. The hemodynamic variables that demonstrated statistical significance were heart rate (HR), systolic blood pressure (SBP), and right atrial pressure (RAP). There was a statistically significant difference in the time from 20% change in HR (median of 0 vs. 1 minute, p<0.001), SPB (median of 0 vs. 4 minutes, *p* =0.004), and RAP (a median of 0 to 14 minutes, *p* = 0.005) until cardiac arrest compared to the time of suctioning in the non-arrest group. Survival to discharge was significantly higher with 97.2% survival in the non-arrest group compared to 53.5% in the arrest group (*p* <0.001).

Table 4. Median (minimum, maximum) for continuous variables, and number (percent) for categorical variables comparing Arrest Group to Non-arrest Group

Patient Demographics (N=135)			
	Non-arrest Group n=36	Total Arrest Group n=99	*p* value
Patient Factors			
Age at Surgery (days)	31 (0, 3646)	34 (1, 5016)	0.819
Gender Male	21 (65.7%)	65 (58.3%)	0.279
Weight (kg)	3.7 (2.3, 43.5)	3.36 (1.1, 53)	0.423
Race			0.32
White	27 (75%)	45 (45.5%)	
Non-white	9 (25%)	54 (54.5%)	
Prematurity	1 (2.8%)	16 (16.2%)	0.038
Insurance			0.445
Private	16 (44.4%)	39 (29.4%)	
Public	8 (22.2%)	33 (30.4%)	
International	12 (33.3%)	27 (27.3%)	

Patient Demographics (N=135)			
	Non-arrest Group n=36	Total Arrest Group n=99	*p* value
STAT			0.074*
STAT low (1, 2,3)	6 (16.7%)	32 (32.3%)	
STAT high (4, 5)	30 (83.3%)	67 (67.7%)	
Non-CHD Congenital anomalies	5 (13.9%)	23 (23.2%)	0.236
System Factors			.
Chemical Paralysis	21 (58.3%)	71 (71.7%)	0.14*
Premedication with lidocaine	5 (13.9%)	3 (3.0%)	<0.001*
Preprocedural Sedation	9 (25%)	7 (7.1%)	<0.001*
Cardiopulmonary bypass time (min)	116.5 (0, 448)	142 (0, 796)	0.08*
Inotrope Score	5 (0, 19)	10 (0, 796)	<0.001*
Preoperative Length of stay	1.91 (0, 41.08)	2.7 (0.5, 48.43)	0.029*
Clinical Factors			
Postop ICU length of stay	9.3 (.93, 67.40)	29.3 (1.09, 245.37)	<0.001*
Heart Rate**	0:00 (0:00, 00:18)	0:01 (0:00, 0:28)	<0.001*
Systolic blood pressure**	0:00 (0:00, 00:29)	0:04 (0:00, 0:29)	0.004*
Diastolic blood pressure**	0:00 (0:00, 00:29)	0:04 (0:00, 00:29)	0.785*
Mean blood pressure**	0:00 (0:00, 00:29)	0:06 (0:00, 0:29)	0.104*
Central venous pressure**	0:17 (0:00, 0:29)	0:15 (0:00,0: 29)	0.469
Right atrial pressure**	0:00 (0:00, 0:28)	0:14 (0:00, 0:29)	0.005*
Left atrial pressure**	0:02 (0:00, 0:21)	0:05 (0:00, 0:23)	0.476
Near-infrared spectroscopy**	0:02 (0:00. 0:21)	0:00 (0:00, 0:29)	0.157*
Pulse Oximetry oxygen saturation**	0:00 (0:00, 0:25)	0:00 (0:00, 0:29)	0.27
Alive at discharge	35 (97.2%)	53 (53.5%)	<0.001*

*p<0.20, variables included in multivariate analysis
** Time in minutes from 20% change in parameter until suctioning and/or arrest

Multinomial Logistic Regression (Aims 1& 2): Multinomial logistic regression was conducted on all variables with a significance level of p≤0.20 in bivariate analysis (Table 4). The cardiac arrest associated with endotracheal suctioning group was used as the reference category. In the comparison of cardiac arrest that occurred not associated with endotracheal suctioning with cardiac arrest associated with endotracheal suctioning, no variables showed statistically significant differences. When the group that experienced suctioning without cardiac arrest was compared to the group that experienced cardiac arrest associated with suctioning, four variables were statistically significantly associated with suctioning (Table 5). For every one minute increase of time in minutes of 20% change in heart rate from baseline, the odds of being in the group that did not experience cardiac arrest were 0.78 times those of being in the group that experienced cardiac associated with endotracheal suctioning (OR: 0.78; 95% CI: 0.62, 0.98; p=0.035). For every one day increase in postoperative intensive care unit length of stay, the odds of being in the group that did not experience cardiac arrest were 0.93 times those of being in the group that experienced cardiac arrest associated with endotracheal suctioning (OR: 0.93; 95% CI: 0.88, 0.97; p =0.003)[Table 6].

Table 5. Multinomial Logistic Regression (Cardiac arrest associated with suctioning is reference group)

Cardiac arrest not associated with endotracheal suctioning				
	p value	Odds Ratio	95% Confidence Interval	
			Lower Bound	Upper Bound
Intercept	0.07			
Male	0.203	2.305	0.638	8.33
Age at time of surgery in days	0.83	1	0.998	1.003
Weight in kilograms	0.75	0.952	0.701	1.291
Non-white	0.057	0.269	0.07	1.037
Not premature	0.191	2.941	0.584	14.808
No Non-CHD anomaly	0.224	0.293	0.041	2.119
STAT 1-3	0.187	3.375	0.555•	20.52
Private Insurance	0.301	2.371	0.462	12.171
Public Insurance	0.46	1.892	0.349	10.265
Inotrope Score	0.49	1.006	0.989	1.024
No chemical paralysis at event	0.229	0.437	0.114	1.682
Preoperative length of stay	0.539	0.979	0.914	1.048
Postoperative ICU length of stay in days	0.495	0.995	0.98	1.01
HR**	0.84	1.013	0.893	1.15
Pulse oximetry oxygen saturation**	0.131	0.935	0.858	1.02
Alive at discharge	0.129	0.301	0.064	1.419

Experienced suctioning but did not experience cardiac arrest				
	p value	Odds Ratio	95% Confidence Interval	
			Lower Bound	Upper Bound
Intercept	0.717			
Male	0.909	1.103	0.205	5.945
Age at time of surgery in days	0.533	0.999	0.996	1.002
Weight in kilograms	0.876	1.025	0.748	1.405
Race non-white	0.125	0.242	0.039	1.483
Not premature	0.334	4.366	0.22	86.683
No Non-CHD anomaly	0.231	0.209	0.016	2.71
STAT 1-3	0.659	0.601	0.062	5.797
Private Insurance	0.43	2.285	0.293	17.825
Public Insurance	0.807	0.759	0.083	6.933
Inotrope Score	0.06	0.889	0.787	1.005
No chemical paralysis at event	0.034*	0.131	0.02	0.855
Preoperative length of stay	0.434	1.042	0.941	1.154
Postoperative ICU length of stay in days	0.003*	0.928	0.883	0.975
HR**	0.035*	0.778	0.616	0.982
Pulse Oximetry oxygen saturation**	0.424	1.059	0.921	1.217
Alive at discharge	0.02*	90.611	2.021	4062.295

*$p<0.05$
** Time in minutes from 20% change in parameter until suctioning and/or arrest

Table 6. Median (minimum, maximum) for continuous variables, and number (percent) for categorical variables comparing Arrest Group associated with suctioning, Arrest not associated with suctioning, and Non-arrest Group

Patient Demographics (N=135)			
	Arrest associated with Suctioning (n=18)	Arrest, Not Suctioning (n=81)	No Arrest (n=36)
Patient Factors			
Age at Surgery (days)	47 (3, 3531)	32 (1, 5016)	31 (0, 3646)
Gender Male	10 (55.6%)	55 67.9%)	21 (58.3%)
Weight (kg)	3.5 (1.1, 26.3)	3.6 (1.54, 53)	3.7 (2.3, 43.5)
Race			
White	12 (66.7)	33 (40.7%)	9(25%)
Non-white	6 (33.3%)	48 (59.3%)	27 (75%)
Prematurity	5 (27.8%)	11 (13.6)	1 (2.8%)
Insurance			
Private	5 (27.8%)	34 (42%)	16 (44.4%)

Patient Demographics (N=135)			
	Arrest associated with Suctioning (n=18)	Arrest, Not Suctioning (n=81)	No Arrest (n=36)
Public	5 (27.8%)	28 (34.6%)	8 (22.2%)
International	8 (44.4%)	19 (23.5%)	12 (33.3%)
STAT Score			
STAT low (1, 2,3)	3 (16.7%)	30 (37%)	6 (16.7%)
STAT high (4, 5)	15 (83.3)	51 (63%)	30 (83.3)
Non-CHD Congenital	2 (7.1%)	21 (25.9%)	5 (3.7%)
Clinical Factors			
Preoperative LOS	4.7 (.56, 32.5)	2.7 (.05, 48.4)	1.91 (0, 41.08)
Postop ICU LOS	38.6 (1.09-151.25)	27 (1.47, 245.37)	9.3 (.93, 67.40)
CPB Time (min)	114 (0, 363)	146 (0, 796)	116 (0, 448)
Inotrope Score	8.7 (0-113)	10 (0, 430)	5 (0, 19)
Chemical Paralysis	9 (50%)	62 (76.5%)	21 (58.3%)
Heart Rate**	0:01 (0:00, 0:04)	0:01 (0:00, 0:23)	0:00 (0:00, 0:18)
Systolic blood pressure**	0:05 (0:00, 0:09)	0:04 (0:00, 0:29)	0:00 (0:00, 0:29)
RAP	0:20 (0:00, 0:28)	0:13 (0:00, 0:29)	0:00 (0:00, 0:28)
Pulse Oximetry oxygen saturation**	0:06 (0:00, 0:26)	0:00 (0:00, 0:29)	0:00 (0:00, 0:25)
Survival to discharge	12 (66.7%)	41 (50.6%)	35 (97.2%)

** Time in minutes from 20% change in parameter until suctioning and/or arrest

Aim 3: This aim examined the events preceding cardiac arrest to determine the incidence of precipitating or exacerbating factors (e.g. procedures, patient care interventions, or pain/agitation) that preceded cardiac arrest events. The nursing and physician EMR notes were reviewed to determine if precipitating or exacerbating factors (Table 3). Events preceding the cardiac event were documented in every record, but only five EMRs referenced agitation as a precipitating event, one event occurred following a portable chest x-ray, and one was related to a painful procedure (peripheral intravenous catheter placement). In seven events, suctioning was the only recorded precipitating event. The remaining events were preceded by common postoperative complications such as bleeding, low cardiac output, arrhythmias, and poor oxygenation and not precipitating or exacerbating factors. There were 99 arrest events; only seven were related to precipitating agitation or painful events yielding insufficient data for further analysis.

Discussion

Several key variables were associated with increased odds of cardiac arrest among children who experienced endotracheal suctioning following surgery for CHD. Specifically, patients who did not experience cardiac arrest associated with suctioning have a decreased odds ratio of experiencing HR change, and absence of chemical paralysis was less likely to be a factor. In the clinical setting, these findings suggest that it is less likely that a clinician will observe a change in HR preceding suctioning in a child who will not experience cardiac arrest; therefore, a change in HR may be a signal of a risk of cardiac arrest associated with suctioning. This information can be included as a factor when assessing the apparent need for endotracheal suctioning against the risk. Chemical paralysis is often present in the postoperative period either as a remaining adjunct of anesthesia or as a strategy to decrease the metabolic demand associated with postoperative recovery. Intracardiac communications persist following many CHD surgeries, leaving patients susceptible to the adverse deviations in cardiopulmonary interaction that may occur when emerging from chemical paralysis combined with endotracheal suctioning. Findings from this study suggest patients experience times of vulnerability either when emerging from chemical paralysis or associated with endotracheal tube suctioning without paralysis. This finding should be confirmed with further with future studies but may be shown to component of practice guidelines developed for endotracheal suctioning.

Additionally, the postoperative length of stay in the intensive care unit was more than 11 days longer among children who experienced cardiac arrest associated with suctioning (mdn= 38.6) compared with children whose cardiac arrest was not associated with suctioning (mdn=27). Risk stratification (STAT) reveals that those that had cardiac arrest associated with suctioning had an higher proportion of STAT 4-5 (83.3%) than cardiac arrest not associated with suctioning (63%); however, those that had suctioning without cardiac arrest also had STAT 4-5 of 83.3% suggesting severity of disease may not be the primary factor in predicting risk of cardiac arrest. This statistically significant finding is also clinically significant because longer length of stay leads to increased resource utilization, charges, and hospital cost.

Inotrope score in the patients who experienced suctioning but did not experience arrest approached statistical significance with p=0.06 and OR 0.889 (0.787, 1.005); lack of reaching statistical significance was likely due to the small sample size. The arrest associated with endotracheal suctioning group was limited, at only 18 events, a larger sample could indicate if this variable is a predictor of likelihood of cardiac arrest. Increased inotrope score correlates to increased inotropic support a patient requires to maintain acceptable physiologic parameters such as blood pressure, heart rate, and evidence of adequate cardiac output that may include adequate urine output, normal renal and liver function test results and skin perfusion. Identification of cut points in the inotrope score that indicate increased risk of cardiac arrest associated with endotracheal suctioning variable would assist in the recognition of high-risk patients prior to suctioning.

Non-white race approached significance with p=0.057 and an odds ratio of 0.269 (0.07, 1.037) in the comparison between patients with cardiac arrest not associated with endotracheal suctioning and patients with cardiac arrest associated with endotracheal suctioning. Non-white patients accounted for 59.3% of arrests not associated with suctioning compared to 33.3% of cardiac arrests that occurred associated with suctioning. Similarly to inotrope score, the lack of significance may be related to small sample size. However, this is an important variable to explore in future research as several studies in CHD have found an increased mortality in minority children (Benavidez, Gauvreau, & Jenkins, 2006; Chan, Pinto, & Bratton, 2012; Nembhard et al., 2013; Oster, Strickland, & Mahle, 2011). Identification of at-risk populations will be an important as mortality has improved over time yet the disparity has remained (Chan et al., 2012). Additionally, many children require CHD surgery early in life and the extent of disparity in mortality was most noted in infancy and early childhood (Nembhard et al., 2013).

Conclusion

Endotracheal suctioning is a routine procedure in pediatric intensive care units throughout the world; establishing practice guidelines to avert cardiac arrest associated with endotracheal suctioning is critical to improving patient outcomes. Findings from this study suggest that children with cardiac arrest experienced a change in heart rate prior to arrest, were not chemically paralyzed, had a longer postoperative ICU length of stay, and had higher mortality than children who experienced suctioning but not cardiac arrest. Despite the increased risk of cardiac arrest in children with CHD, the incidence remains low, with arrest associated with suctioning occurring even less commonly. This is one of the limitations of this study, a small sample size. This was an anticipated limitation as cardiac arrest is relatively infrequent in high volume, high performing center; therefore, this was an exploratory analysis using the available sample size. Every record did include precipitating events but few were related to noxious stimuli. This may indicate difference in sedation standards resulting in fewer incidences of agitation related events. A multisite study may reveal a different incidence. The bivariate analyses comparing the non-arrest and total arrest group demonstrated statistical significance in premedication with endotracheal lidocaine and pre-procedural sedation. This did not reveal significance in the logistic regression. This is also an area for further research in a larger data set. Another limitation of this study is the limited data indicating ventilation parameters. Retrospective data only contained continuous measures of pulse oximetry oxygen saturation. This limited the data that may suggest alterations in pulmonary blood flow. Newer data interface software transmit the continuous ventilator monitoring data, including measures such as mean airway pressure, tidal volume, end tidal carbon dioxide, to the physiologic monitor. Utilization of this data in future work will likely increase the understanding of the cardiopulmonary interaction associated with endotracheal suctioning.

Findings from this exploratory study will inform a power analysis to determine the appropriate sample size for an adequately powered future multisite study. Tracking, Trajectory, and Trigger [T^3], Etiometry is currently in use in 16 intensive care units located in seven hospitals in the United States, Canada, and Great Britain. A multicenter trial will leverage the experience of multiple units experiencing this infrequent event to identify further clinical signals of risk of cardiac arrest associated with endotracheal suctioning.

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Summary

This dissertation consists of three manuscripts: (1) the effect of endotracheal suctioning in the pediatric population: an integrative review, using the Neuman systems model as the theoretical framework; (2) instruments for risk adjustment in congenital heart disease: an integrative review, with knowledge-to-action providing a theoretical framework; (3) cardiac arrest associated with endotracheal suctioning following surgery for congenital heart disease, using cardiopulmonary interaction as a conceptual framework. This dissertation establishes the groundwork for further research on the effect of endotracheal suctioning in children with congenital heart disease, with the long-term objective of developing and implementing interventions to avert or forestall cardiac arrest.

The integrative review of the literature on the effect of endotracheal suctioning in pediatrics synthesized 14 articles that met the inclusion criteria. This review found that the studies centered on three areas: the effect of suctioning on the neurovascular system, the effect of suctioning on the respiratory system, and suctioning as proxy for painful procedures to validate pain assessment tools. Many studies excluded children with congenital heart disease; 67% of studies were conducted with premature neonates. Some studies measured hemodynamic variables, but these were often collected as measures of effectiveness of interventions rather than to investigate the physiological effect of suctioning. The single study that specifically examined the effect of physiological effect of endotracheal suctioning reported the changes in airway dynamics but did not examine the hemodynamic effects of suctioning. Consequently, current suctioning recommendations for children have been derived from adult studies or small general pediatric studies (Gillies & Spence, 2011; Morrow & Argent, 2008; Pritchard et al., 2001; Taylor et al., 2011; B. K. Walsh et al., 2011). This review demonstrated a gap in the literature on the effect of suctioning on the child with congenital heart disease.

The integrative review that followed was conducted to identify tools for risk adjustment in cardiac surgery. This allows researchers and clinicians to compare different case types with similar risk of mortality. Unlike adult cardiac surgery, congenital heart surgery is very heterogeneous with more than 100 operative procedure types. Risk stratification is necessary to achieve feasible categories for comparison. This review included 25 articles encompassing five tools for risk adjustment in congenital heart surgery. Five tools were identified; three tools are based on surgical complexity, one on the intensity of postoperative pharmacological support, and the last measures the outcome of the surgical repair. All tools demonstrated effectiveness in their ability to measure risk of mortality with differing data and resource requirements. Results of this review suggest clinicians and researchers should utilize a tool that is feasible to apply and aligns with their area of research.

The examination of cardiac arrest associated with endotracheal suctioning following surgery for congenital heart disease was a retrospective study to first, determine the characteristics of pediatric congenital heart surgery patients who experienced cardiac arrest during endotracheal suctioning compared to those whose cardiac arrest was not during suctioning and those who experienced suctioning without cardiac arrest. Secondly, the study aimed to identify the changes in physiologic parameters in intubated pediatric CHD patients 30 minutes prior to suctioning, and lastly, to examine the events preceding cardiac arrest to determine potential precipitating or exacerbating factors (e.g. procedures, patient care interventions, or pain/agitation). The study included 99 cases of cardiac arrest that occurred either during endotracheal suctioning or not associated with suctioning. An additional 36 cases experienced endotracheal suctioning but did not experience cardiac arrest. Summary statistics were used to describe the arrest events (99), both during suctioning and not during suctioning to the suction events that did not experience cardiac arrest (36). This analysis demonstrated a difference between the groups corroborating the hypothesis that the groups do contain differences which with further analyses may reveal variables that signal risk of cardiac arrest associated with endotracheal suctioning. Subsequently, the three groups, pediatric congenital heart surgery patients who experienced cardiac arrest during endotracheal suctioning (n=18) compared to those whose cardiac arrest was not during suctioning (n=81) and those who experienced suctioning without cardiac arrest (n=36). Multinomial logistic regression was performed with all variables with a p value <0.20 from bivariate analysis with cardiac arrest during endotracheal suctioning as the reference variable. An increase or decrease of 20% in a physiologic parameter from the baseline value 30 minutes prior to suctioning or arrest was considered hemodynamically significant. The time in minutes of an increase or decrease of 20% in a physiologic parameter prior to endotracheal suctioning was calculated. Heart rate was the only hemodynamic variable with a statistically significant association with those that experienced cardiac arrest associated with suctioning compared to those that experienced suctioning but did not experience cardiac arrest. Additional variables that were significant in the final model were chemical paralysis at the time of suctioning, postoperative intensive care unit length of stay, and survival to discharge.

Limitations

Despite having five years of data for our retrospective study, the number of children under 18 years of age experiencing cardiac arrest was small, which limited the statistical analyses. This was an anticipated potential problem; however, this was an exploratory analysis using a given sample size. Both race and inotrope score approached significance but remained with a $p>0.05$; this may be due to the small sample size. Three events did not have retrievable data in the Etiometry T^3 data analytics platform and could not be included in the analyses which further reduced the available data. The purpose of Aim 3 was to determine the incidence of precipitating or exacerbating factors, specifically procedures, patient care interventions, or pain/agitation. The effect of noxious stimuli to induce hemodynamic labiality in the CHD patient is known, but whether such stimuli play a significant role in hastening cardiac arrest is not known (Ofori-Amanfo & Cheifetz, 2013). Every record documented the actions preceding the cardiac event but only five referenced agitation, one cardiac arrest followed a portable chest x-ray, and one was related to a painful procedure (peripheral intravenous catheter placement). Suctioning was the only precipitating action in seven additional cardiac arrest events. The remaining events (n = 85) were associated with predictable postoperative complications, e.g. bleeding, low cardiac output, arrhythmias, and poor oxygenation. These limitations demonstrate the importance of using these pilot data to inform power analyses for future research.

Importance of Theoretical Framework

The effects of endotracheal suctioning in the pediatric population: an integrative review utilized the Neuman Systems Model. The Neuman Systems model views the wellness of a patient as a continuum ranging from wellness to illness (Neuman, 2001; Neuman & Fawcett, 2011). This continuum is affected by environmental stressors that push a patient away from wellness. The environment components consist of: the internal environment, that which occurs within the client and the external environment, that which occurs outside of the client (Neuman, 2001). Children requiring care in an intensive care unit experience many interventions that affect both the internal and external environment. Following cardiac surgery, the internal environment may be markedly altered, potentially influencing the wellness continuum and the response to common care events such as suctioning. Additionally, the external stressors such as pain, agitation, fear, cold, and the same patient care interventions can adversely affect the wellness continuum. The Neuman model offers a whole patient approach, which promotes a thorough evaluation of the environment to identify causative influences and form protective strategies.

Instruments for Risk Adjustment in Congenital Heart Disease: An Integrative Review employed the Knowledge-to-Action theoretical framework. The Knowledge-to-Action theoretical framework consists of three phases: knowledge inquiry, synthesis of knowledge, and development of knowledge tools in response to an identified problem (Graham et al., 2006; Straus et al., 2011). This framework guided the identification available tools for risk stratification in CHD. Annually, there are over 33,000 surgeries performed for CHD but, in contrast to adult cardiac surgery, there are numerous operative procedures for CHD with proportionally fewer cases (Barach et al., 2008; Jacobs et al., 2009). It is necessary to provide a degree of homogeneity across these numerous procedures to compare outcomes, evaluate interventions and report generalizable research (Lacour-Gayet, Clarke, Jacobs, Gaynor, et al., 2004). The Knowledge-to-Action theoretical framework provided a structure to conduct a knowledge inquiry and then perform a synthesis of the available tools.

The exploratory study to investigate cardiac arrest associated with endotracheal suctioning following surgery for congenital heart disease, utilized cardiopulmonary interaction as the conceptual framework. The effect of cardiopulmonary interaction and the influence of endotracheal suctioning on that interaction can have great variability in children with CHD. Normal cardiopulmonary function involves the interaction of pressures and flow both inside and outside of the heart (Bronicki & Anas, 2009). In CHD, there are many components that affect pressure and flow that can result in a decrease in ventricular filling. The interaction may result in shunting of blood, via septal openings, away from the lungs resulting in hypoxemia; or conversely, away from the body, resulting in low cardiac output due to the lack of available blood (Bronicki & Anas, 2009; Bronicki & Chang, 2011; Kocis & Meliones, 2000; Ofori-Amanfo & Cheifetz, 2013). This conceptual framework guided the selection of study variables, including hemodynamic monitoring parameters, which reflect the changes in cardiopulmonary interactions. Understanding how routine cares adversely affect cardiopulmonary interaction is an important component in implementing preemptive interventions.

Research Trajectory

The next steps in researching the effects of suctioning on individuals with congenital heart disease is to use the data from this exploratory study to inform a power analysis for a future larger study and then partner with other institutions that also care for these patients to conduct a multisite study. Tracking, Trajectory, and Trigger [T3], Etiometry, the data collection software that was used in this study, is currently in use in 16 intensive care units located in seven hospitals in the United States, Canada, and Great Britain. A multicenter trial will leverage the experience of multiple units experiencing this infrequent cardiac arrest event to answer the research questions left unanswered in this dissertation. Further, in October of 2016, Etiometry received FDA clearance for use of a risk analytics algorithm for inadequate oxygen delivery (iDO2) in neonates. This new marker can be added as a variable in future studies to evaluate if it is a signal for increased risk of cardiac arrest during suctioning. Additionally, new technology inputs ventilation parameters from the mechanical ventilator to the hemodynamic monitor in real time where it is recorded into the T3 analytics platform. Previously, bedside staff manually recorded this information every 2-4 hours, leaving long gaps in data. As children with CHD can have rapid detrimental changes in their cardiopulmonary interactions, having continuous access to ventilation data demonstrating airway pressures, volumes, and inspiratory/expiratory gases will add valuable information. The cardiac intensive care unit has an increasing population of adults with congenital heart disease (ACHD) that were excluded from this work. Many with ACHD are vulnerable to the same adverse alterations in cardiopulmonary interaction associated with suctioning. This will be an important population to examine in future studies. Data from these studies can be used to develop practice guidelines to improve quality of care.

Contribution to Nursing and Interprofessional Sciences

Current literature on endotracheal suctioning focuses on pain as a result of the practice, efficacy of suctioning technique, and the effect on specific patient populations, such as preterm infants and children with traumatic brain injury (Cone et al., 2013; Cury et al., 2013; Evans et al., 2014; Gillies & Spence, 2011; Kaiser et al., 2008, 2011; Karpe et al., 2013; Limperopoulos et al., 2008; Peyrovi et al., 2014; Pirr et al., 2013; Pritchard et al., 2001; Rieger et al., 2005; Sonmez Duzkaya & Kuguoglu, 2015; Spence et al., 2003; Taylor et al., 2011; Tume et al., 2011; B. K. Walsh et al., 2011). The literature on cardiac arrest in children with CHD is primarily focused on incidence of cardiac arrest, resuscitation procedures, and patient outcomes (Bloom et al., 1997; Chrysostomou et al., 2013; Duncan et al., 1998; Ferguson et al., 2012; Jindal et al., 2011; Kalloghlian et al., 1998; Lowry et al., 2013; Ma et al., 2007; Mahle et al., 2001; Parra et al., 2000; Peddy et al., 2007; Rhodes et al., 1999; Timerman et al., 2001). Many studies were retrospective and identified characteristics such as age, weight, and diagnoses that were associated with increased prevalence of cardiac arrest from all causes. The literature also includes educational articles on resuscitation considerations specific to patients with CHD; however, these focus on resuscitation procedures rather than prevention of arrest (Parra et al., 2000; Peddy et al., 2007). Patient survival, neurological impact, and other sequalae of arrest have also been studied. The data analysis generally begins at the time of arrest and examines the interventions during arrest and outcomes following cardiac arrest. Moreover, current postoperative care standards in CHD such as inotrope management, ventilation strategies, and sedation management are not included as variables in the cardiac arrest literature, despite the fact that these factors are considered in everyday nursing care. The literature on cardiac arrest has focused on patient characteristics, nursing perception of acuity, and patient outcomes. Other literature describing cardiopulmonary interactions in children with CHD did not examine the effect of endotracheal suctioning on cardiopulmonary interaction (Bronicki & Anas, 2009; Bronicki & Chang, 2011; Kocis & Meliones, 2000). Educational articles on resuscitation considerations specific to patients with CHD focused on resuscitation procedures rather than prevention of arrest (Parra et al., 2000; Peddy et al., 2007). Data analyses generally start at the time of arrest and examine the interventions and outcomes following cardiac arrest.

In contrast, this dissertation study examined data prior to arrest to identify predictive factors. Among patients who arrested, those who arrested during suctioning (versus no suctioning) were more likely to have a 20% change in heart rate, and less likely to have had chemical paralysis as well a significantly longer intensive care unit length of stay. These findings suggest a particular time of vulnerability in the pediatric CHD patient. The results of this study will not only be significant for children with CHD, but also to clinicians, including nurses, physicians, and respiratory therapists caring for critically ill children with and without CHD.

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Institutional Review Board for Human Research (IRB)

Office of Research Integrity (ORI)

Medical University of South Carolina

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19 Hagood Ave., Suite 601, MSC857

Charleston, SC 29425-8570

Federal Wide Assurance # 1888

Pro00057694

Hemodynamic variability preceding cardiac arrest associated with endotracheal suctioning compared to cardiac arrest unrelated to endotracheal suctioning in children following surgery for congenital heart disease

Submitted by: **Anna Fisk**

Department: **Medical University of South Carolina**

Sponsor Protocol Version: **Hemodynamic Variability Preceding Cardiac Arrest**

Dated: **5/25/2016**

Facilitated Review Acceptance Date:

CIRB Approval Expiration:

Type: **Facilitated Review**

Facilitated Review Date: August 3, 2016

The MUSC IRB agreed to rely on the Boston Children's Hospital IRB for the review and continuing oversight for its human subjects research for this study.

IRB Manager, **Medical University of South Carolina**

Stacey C. Goretzka, CIP∗

∗***Electronic Signature****: This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*

Boston Children's Hospital
Institutional Review Board (IRB)
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Principal Investigator	Ravi Thiagarajan, MD
Protocol Number	IRB-P00022057
Protocol Title	Hemodynamic variability preceding cardiac arrest associated with endotracheal suctioning compared to cardiac arrest unrelated to endotracheal suctioning in children following surgery for congenital heart disease
Date:	June 21, 2016

NOTICE OF EXPEDITED APPROVAL

IRB Approval Date:	**6/21/2016**
IRB Activation/Release Date:	**6/21/2016**
IRB Expiration Date:	**6/20/2017**

The Institutional Review Board has approved the above referenced protocol through expedited review procedures as permitted under 45 CFR 46.110, category 5.

Risks were determined to be minimal with no potential for direct benefit.

The IRB has determined that you have met the regulatory requirements necessary in order to obtain a waiver of informed consent/authorization.

The occurrence of unanticipated problems should promptly be reported to this office. Any revisions, amendments, or changes to the protocol require prior IRB approval. The IRB has asked this office to notify investigators that clinical investigation protocol files are subject to audits at some future time.

Sincerely,

Ashley Kuniholm, CIP
IRB Administrator
For the Institutional Review Board

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