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RISK FACTORS ASSOCIATED WITH PRESSURE INJURY IN PEDIATRIC
CONGENITAL HEART DISEASE PATIENTS

A Dissertation

School of Nursing

Duquesne University

In partial fulfillment of the requirements for
the degree of Doctor of Philosophy

By

Ashlee Shields

May 2020

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Ashlee Shields

2020

RISK FACTORS ASSOCIATED WITH PRESSURE INJURY IN PEDIATRIC
CONGENITAL
HEART DISEASE PATIENTS

By

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ABSTRACT

RISK FACTORS ASSOCIATED WITH PRESSURE INJURY IN PEDIATRIC CONGENITAL HEART DISEASE PATIENTS

By

Ashlee Shields

May 2020

Dissertation supervised by Dr. Lynn Simko

Pediatric congenital heart disease (CHD) patients have unique risk factors associated with the pathophysiology of abnormal heart function. This vulnerable population is likely at an increased risk of acquiring a pressure injury during hospitalization. There are limited studies that include congenital heart disease patients and more specifically, factors unique to these patients. The purpose of this study was to identify risk factors associated with development of pressure injury in pediatric CHD patients. This retrospective study used a convenience sample from hospital-acquired data including subjects with congenital heart disease. The results demonstrated an association between pressure injury development and variables both known in literature and those specific to the population. Corticosteroid and anticoagulation use were most likely to

result in the development of a pressure injury. The study findings inform nursing practice and demonstrate a need to implement further prevention practices.

Keywords: *congenital heart, pressure injury, pediatric*

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Chapter One

Problem

Patients with congenital heart diseases or heart failure have unique variables associated with the pathophysiology of a poorly functioning heart or altered anatomy, making patients susceptible to pressure injury from factors associated with their condition or treatment. These factors include but are not limited to pathological anatomy and function, hypoxemia, pharmacologic-related risk, edema, medication inhibiting skin integrity, and extracorporeal membrane oxygenation (ECMO) support. Physiologic differences exist between congenital heart patients and those with normal cardiac anatomy and hemodynamics, affecting adequate perfusion and oxygen consumption/delivery by tissues. In the limited studies that included pediatrics, patients with congenital heart defects were excluded (Curley, Quigley, & Lin, 2003; Curley, Razmus, Roberts, & Wypij, 2003; Quigley & Curley, 1996). Congenital heart disease (CHD) patients were excluded from Curley et al.'s study because of chronic hypoxemia and the unclear role this plays in pressure injury development (Curley, Razmus, et al., 2003). In a recent study, pediatric cardiac patients were included to test the ability to predict pressure injuries with medical devices (Curley, Quigley, Noonan, McCabe, & Wypij, 2018). Pressure ulcers are commonly seen in critical care patients because of hemodynamic instability, vasoactive drugs, and devices related to care (The Joint Commission, 2016). Therefore, it is important to understand the etiology of pressure injuries to make changes in practice to prevent future occurrences of pressure injuries.

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Background

There are an estimated 2.5 million patients per year who acquire a pressure ulcer during their hospital stay from the report of The Institute for Healthcare Improvement (2014). The annual cost for treating pressure injuries in the United States is approximately \$11 billion (Improvement, 2014). In addition to the financial expense; pain and suffering experienced by patients while treating pressure injuries is immeasurable. Among these patients who acquire pressure injuries are critically ill neonates and children. Across the lifespan, hospitalized patients are evaluated for pressure injury risk development using a validated tool such as the Braden or Norton scales. While experts such as The National Pressure Ulcer Advisory Panel (2014) recommend using a structured approach to risk factor assessment, they do not specify the pressure injury risk assessment tool that should be used. This organization evaluated available expert evidence related to risk factor assessment including: assessment of activity/mobility and skin status, perfusion and oxygenation, nutritional status, increased skin moisture and potential impacts related to increased body temperature, advanced age, sensory perception, hematological measures and general health status (National Pressure Ulcer Advisory Panel, 2014). The recommendations from National Pressure Ulcer Advisory panel for preventive skin care include: incontinence management, keeping the skin clean and dry, avoid positioning on an area of erythema, protect skin from excessive moisture, and using a skin moisturizer to hydrate skin when necessary (National Pressure Ulcer Advisory Panel, 2014). Interventions can be implemented to prevent pressure ulcers including: adequate nutrition, individualized care plan, repositioning and early mobilization, and appropriate support surfaces (National Pressure Ulcer Advisory Panel, 2014).

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There are recommendations for special populations (bariatric, critically ill, older adults, operating room, palliative care, pediatrics, and spinal cord injury) to be used within the context of the general prevention guidelines (National Pressure Ulcer Advisory Panel, 2014). There are no specific guidelines or recommendations available for cardiac patients across the lifespan.

While these guidelines and recommendations address basic assessment needs, risk factors, and preventative treatment, further research is needed to define variables associated with pressure injury development in disease specific populations such as neonates and children with congenital heart disease and/or heart failure. Guidelines for pressure injury care and management in pediatrics have been adopted from adult data due to the scarcity of studies from pediatric groups (Bernabe, 2012; Curley, Quigley, et al., 2003; Curley, Razmus, et al., 2003; Quigley & Curley, 1996). In addition, patients with unique conditions such as congenital heart disease will need additional measures taken and special care provided to prevent pressure injury. However, risk factors need to be assessed to better protect these patients.

Purpose

The risk factors associated with pressure injury development in pediatric congenital heart disease patients are neither well defined nor evaluated through research. Due to the paucity of available references, adult data was included in this review to identify risk factors among cardiac patients. The purpose of this study is to examine risk factors associated with acquiring a pressure injury in the cardiac patient population across the lifespan and examine if pediatric cardiac patients are at a greater risk than those with normal cardiac pathophysiology and function.

Significance of the Study

Cardiac patients have unique risk factors associated with the pathophysiology of abnormal heart function. Since they are likely at increased risk for developing pressure injury

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during hospitalization, health care providers must adopt prevention practices according to their unique physiology. Adult and general pediatric skin care bundles warrant evaluation and refinement to enhance their specificity for pediatric cardiac patients. Considerations must include evidence-based tiered protocols that include prevention plans of care, frequent turning and use of specialty surfaces that are tailored to align pressure redistribution qualities with altered perfusion and hemodynamic status. Advanced technologies are associated with multiple medical devices, a newer and necessary focus for pressure injury prevention in children. Head-to-toe skin assessment should be scheduled and collaborative, inclusive of certified wound ostomy nurses. Lastly, product cost (e.g., fluidized positioners) should be conscientiously weighed against the harm, pain and disfigurement of pressure injury.

Assumptions

Hospital acquired pressure injuries is a problem that will never be resolved. In this study the authors assumes medical record charting is accurate and not limited due to omissions within the subjects' chart. The number of available subjects will be enough to demonstrate the risk of acquiring a pressure ulcer in the congenital heart disease population.

Limitations

A retrospective study does not permit characterization of the study cohort as precisely and accurately as a well-executed prospective study. We depended on the data recorded by physicians and nurses who were responsible for care. This study will be limited to one freestanding tertiary urban care center. A convenience sample will be used based on a defined period and may also include a limited number of subjects in each group. This study cannot be generalized to a larger population and the findings will only be suggestive. Since this study data

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is from a limited period of time, there could be limitations the researcher is unaware of such as changes in practice, products, or specialty beds available.

Operational Definitions

1. Age- Age in months on admission to hospital.
2. Anticoagulation- Medication that is used to prevent blood clotting. (yes/no)
3. Body Temperature- Subjects body temperature in Celsius in the 24 hours prior to pressure injury or lowest temperature during admission.
4. Corticosteroids- Continuous or intermittent steroids a subject received either during the hospital stay prior to acquiring a pressure injury. (yes/no)
5. Cardiac Disease Category- CHeSS (Congenial Heart Surgical Stay) category is a tool to analyze the risk for mortality (death). The category is also used to predict extended cardiac ICU length of stay following surgery for congenital heart disease.
6. Tissue Perfusion and Oxygenation During ICU Admission-
In the 24 hours prior to pressure injury development or during admission:
 - i. Lowest Pulse oximetry
7. Tissue Perfusion and Oxygenation During ICU Admission-
In the 24 hours prior to pressure injury development or during admission:
 - i. Systolic blood pressure (SBP) associated with the lowest diastolic blood pressure (DBP) (mmHg)
8. Tissue Perfusion and Oxygenation During ICU Admission-
In the 24 hours prior to pressure injury development or during admission:
 - i. Lowest Hemoglobin (Hgb)
9. Tissue Perfusion and Oxygenation During ICU Admission-

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In the 24 hours prior to pressure injury development or during admission:

- i. Hematocrit (Hct) gm/dL
10. Albumin level (g/dL) in the three days prior to pressure injury development or lowest during ICU admission.
11. Repeated procedures or combination of procedures-
 - a. Subject requiring repeated operative or diagnostic procedures in 3 days and/or 24 hours prior to pressure injury development (yes/no) or did the patient have repeated operative or diagnostic procedures during their ICU stay?
12. Pressure injury- A pressure injury is localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. (NPUAP, 2016)
 - a. Did the patient acquire a pressure injury? (yes/no)
13. Sex- Male or Female
14. Surgery- Subject who developed a pressure injury and had a surgery/procedure within 7 days prior. (yes/no)
 - a. Length of time on cardiopulmonary bypass- Time in minutes on bypass from initiation to end.
 - b. Length of time in minutes in operative or procedural room.
 - c. Length of operation or procedure in minutes.
 - d. Tissue Perfusion and Oxygenation During Operative Procedure- (only if patient was in the operating room in the 7 day prior to pressure injury development):
 - i. Lowest pulse oximetry
 - ii. Lowest Mean Blood Pressure (mmHg)

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- iii. Portion of operating room time a patients mean pressure was low (minutes)
- iv. Systolic blood pressure associated with the lowest DBP (mmHg)
- v. Lowest Hemoglobin (Hgb) and Hematocrit (Hct) in gm/dL
- vi. Lowest body temperature (Celsius)

Research Questions

1. What risk factors are associated with pressure injury development in pediatric patients with congenital heart disease?
2. What is the probability of pediatric cardiac ICU patients acquiring a pressure injury based on significant risk factors?
3. Do pediatric cardiac patients who acquire a pressure injury have a higher CHeSS category score?
4. What risk factors are associated with pressure injury development in pediatric patients with congenital heart disease who have undergone cardiac surgery?

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Figure 1.1

CHeSS Categories

CHeSS Category 1		
Generator Change	PAB with SLL transposition (b)	Williams syndrome repair
ASD/PFO primary closure or patch	Senning/Mustard for D-TGA	TOF repair + RV-PA conduit + MAPCA (d)
Vascular ring repair	Konno procedure	Complete AVC + TOF repair, Trisomy 21 (c)
Pulmonary valve replacement	Supravalvular AS repair	Double switch L-TGA/VSD
ASD primum repair	VSD + pulmonary artery band removal	Unifocalization with BTS on CPB
Subvalvar AS repair, no myectomy	Double switch for L-TGA/IVS	Left ventricle rehabilitation
Coarctation repair, end-to-end, ≥ 1 month (a)	Ebstein's repair	DORV + RVOT repair
Tumor		Tricuspid valvuloplasty, with single ventricle (b)
Pulmonary valvotomy	CHeSS Category 3	Rastelli/Senning for L-TGA/VSD
Unroofing of coronary artery	Isolated Fontan (d)	Complete AVC repair, no Trisomy 21 (c)
Supravalvular mitral ring or cor triatriatum repair	Tricuspid valvuloplasty + RV-PA conduit change (d)	Repair TOF/PA with RV-PA conduit (d)
Transitional AVC repair	BDG + additional procedure, non-AW repair (d)	Tricuspid valve replacement
Aortic or truncal valvuloplasty	Mitral or AVV valvuloplasty, no aortic valve repair (d)	Palliative repair for TOF/PA/MAPCA
Subvalvar AS repair + myectomy for IHSS	Isolated atrial septectomy	
Ascending aortic graft	Coarctation repair, end-to-end, < 1 month (a)	CHeSS Category 5
PDA closure (not premature)	Complete AVC repair, Trisomy 21 (c)	DORV + systemic shunt + PDA closure
LVOT repair or enlargement	ALCAPA repair	Mitral or AVV replacement < 5 years
	Ross procedure	BDG + AVV repair (d)
	Mitral AVV valvuloplasty + aortic valve repair (d)	Damus-Kaye-Stansel procedure
CHeSS Category 2	TOF repair- absent pulmonary valve	ASO for D-TGA/VSD and PAB takedown
Tricuspid valvuloplasty + RVOT procedure (d)	DORV intraventricular tunnel repair	Modified Blalock-Taussig Shunt (MBTS)
Aortic or truncal valve replacement	Unifocalization without bypass	VSD repair + ADS repair + coarctation repair
Conduit reoperation	Isolated arch repair on CPB	ASO + VSD repair
Isolated VSD primary closure	Multiple VSD primary closures	Pulmonary vein stenosis repair
Epicardial pacemaker		Nikaidoh procedure for TGA/VSD/PS
Tricuspid valvuloplasty + non-RVOT procedure (d)	CHeSS Category 4	Complete AVC repair + TOF repair, no Trisomy 21(c)
RV muscle resection for SCR	Ross-Konno procedure	Biventricular repair
AP window	TAPVC repair, ≥ 1 week (a)	ASO + VSD repair + coarctation repair
Isolated BDG (d)	Reimplantation/isolated pulmonary artery	PAB, no SLL transposition (b)
Isolated tricuspid valvuloplasty (d)	TOF repair - transannular patch	Truncus arteriosis repair
TOP repair- nontransannular patch	Fontan + AVV repair (d)	TAPVC repair, 1 < week (a)
Aortic root replacement	Comprehensive stage 2	
	ASO for D-TGA/IVS	

Figure 1. Procedures in each Congenital Heart Surgical Stay (CHeSS) category. ALCAPA = anomalous left coronary from the pulmonary artery, AP = aortopulmonary, AS = aortic stenosis, ASD = atrial septal defect, ASO = arterial switch operation, AVC = atrioventricular canal, AVV = atrioventricular valve, BDG = bidirectional Glenn, BTS = Blalock-Taussig shunt, CPB = cardiopulmonary bypass, DCRV = double-

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chambered right ventricle, DORV = double outlet right ventricle, D-TGA = dextro transposition of the great arteries, IHSS = idiopathic hypertrophic subaortic stenosis, IVS = intact ventricular septum, L-TGA = levo transposition of the great arteries, LVOT = left ventricle outflow tract, MAPCA = major aortopulmonary collateral artery, PA = pulmonary atresia, PAB = pulmonary artery band, PDA = patent ductus arteriosus, PFO = patent foramen ovale, PS = pulmonary stenosis, RV = right ventricle, RVOT = right ventricle out or tract, RV-PA = right ventricle to pulmonary artery, SLL = Situs solitus with L-looped ventricles and levoposition of great arteries, TAPVC = total anomalous pulmonary venous connection, TGA = transposition of the great arteries, TOF = tetralogy of fallot, VSD = ventricular septal defect. (a) stratified by age, (b) stratified by diagnosis, (c) stratified by genetic syndrome, and (d) stratified by secondary procedure.

Chapter Two

Introduction

There are an estimated 2.5 million patients per year who acquire a pressure ulcer during their hospital stay from the report of The Institute for Healthcare Improvement (2014). The annual cost for treating pressure injuries in the United States is approximately \$11 billion (Improvement, 2014). In addition to the financial expense, pain and suffering experienced by patients while treating pressure injuries is immeasurable. Among these patients who acquire pressure injuries are critically ill neonates and children. Across the lifespan, hospitalized patients are evaluated for pressure injury risk development using a validated tool such as the Braden or Norton scales. While experts such as The National Pressure Ulcer Advisory Panel (2014) recommend using a structured approach to risk factor assessment, they do not specify the pressure injury risk assessment tool that should be used. This organization evaluated available expert evidence related to risk factor assessment including: assessment of activity/mobility and skin status, perfusion and oxygenation, nutritional status, increased skin moisture and potential impacts related to increased body temperature, advanced age, sensory perception, hematological measures and general health status (National Pressure Ulcer Advisory Panel, 2014). The recommendations from National Pressure Ulcer Advisory panel for preventive skin care include: incontinence management, keeping the skin clean and dry, avoid positioning on an area of erythema, protect skin from excessive moisture, and using a skin moisturizer to hydrate skin when necessary (National Pressure Ulcer Advisory Panel, 2014). Interventions can be implemented to prevent pressure ulcers including: adequate nutrition, individualized care plan, repositioning and early mobilization, and appropriate support surfaces (National Pressure Ulcer Advisory Panel, 2014).

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There are recommendations for special populations (bariatric, critically ill, older adults, operating room, palliative care, pediatrics, and spinal cord injury) to be used within the context of the general prevention guidelines (National Pressure Ulcer Advisory Panel, 2014). There are no specific guidelines or recommendations available for cardiac patients across the lifespan.

While these guidelines and recommendations address basic assessment needs, risk factors, and preventative treatment, further research is needed to define variables associated with pressure injury development in disease specific populations such as neonates and children with congenital heart disease and/or heart failure. Guidelines for pressure injury care and management in pediatrics have been adopted from adult data due to the scarcity of studies from pediatric groups (Bernabe, 2012; Curley, Quigley, et al., 2003; Curley, Razmus, et al., 2003; Quigley & Curley, 1996). In addition, patients with unique conditions such as congenital heart disease will need additional measures taken and special care provided to prevent pressure injury. However, risk factors need to be assessed to better protect these patients.

Problem Identification

Patients with congenital heart diseases or heart failure have unique variables associated with the pathophysiology of a poorly functioning heart or altered anatomy, making patients susceptible to pressure injury from factors associated with their condition or treatment. These factors include but are not limited to pathological anatomy and function, hypoxemia, pharmacologic-related risk, edema, medication inhibiting skin integrity, and extracorporeal membrane oxygenation (ECMO) support. Physiologic differences exist between congenital heart patients and those with normal cardiac anatomy and hemodynamics, affecting adequate perfusion and oxygen consumption/delivery by tissues. In the limited studies that included pediatrics, patients with congenital heart defects were excluded (Curley, Quigley, et al., 2003;

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Curley, Razmus, et al., 2003; Quigley & Curley, 1996). Congenital heart disease (CHD) patients were excluded from Curley et al.'s study because of chronic hypoxemia and the unclear role this plays in pressure injury development (Curley, Razmus, et al., 2003). In a recent study, pediatric cardiac patients were included to test the ability to predict pressure injuries with medical devices (Curley et al., 2018) Pressure ulcers are commonly seen in critical care patients because of hemodynamic instability, vasoactive drugs, and devices related to care (The Joint Commission, 2016). Therefore, it is important to understand the etiology of pressure injuries to make changes in practice to prevent future occurrences of pressure injuries.

Purpose of Integrative Review

The risk factors associated with pressure injury development in pediatric congenital heart disease patients are neither well defined nor evaluated through research. Due to the paucity of available references, adult data was included in this review to identify risk factors among cardiac patients. The purpose of this integrative review is to examine the risk factors associated with acquiring a pressure injury in the cardiac patient population across the lifespan.

Significance of the Study

Cardiac patients have unique risk factors associated with the pathophysiology of abnormal heart function. Since they are likely at increased risk for developing pressure injury during hospitalization, health care providers must adopt prevention practices according to their unique physiology. Adult and general pediatric skin care bundles warrant evaluation and refinement to enhance their specificity for pediatric cardiac patients. Considerations must include evidence-based tiered protocols that include prevention plans of care, frequent turning and use of specialty surfaces that are tailored to align pressure redistribution qualities with altered perfusion and hemodynamic status. Advanced technologies are associated with multiple medical devices, a

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newer and necessary focus for pressure injury prevention in children. Head-to-toe skin assessment should be scheduled and collaborative, inclusive of certified wound ostomy nurses. Lastly, product cost (e.g., fluidized positioners) should be conscientiously weighed against the harm, pain and disfigurement of pressure injury.

Methods

This integrative review process from Whittmore and Knafl (2005) was used to evaluate the literature. This framework consists of five stages: problem identification, literature search, data evaluation, analysis, synthesis, and presentation of the findings. The integrative review stages were used to answer the following research question: What risk factors are associated with the development of pressure injuries in cardiac patients across the lifespan?

Literature Search

Scientific papers were searched in PubMed, CINAHL (Cumulative Index to Nursing and Allied Health), and Scopus databases. Searches were performed using the keywords *Cardiac surgery, Cardiac patients, Cardiac disease, or Cardiac bypass surgery, and Pressure ulcer, Pressure sore, Bedsore, Deep-tissue injury, Decubitus ulcer, Skin, or Skin breakdown*, appearing in either the title or abstract. Due to the paucity of available information, literature was searched through August 2017. Papers were also searched by hand in the journals *American Journal of Critical Care, Critical Care Nurse, and Wound, Ostomy, and Continence from January 2012-August 2017*. New relevant papers were not found using the hand searching method. The gray literature was not searched for unpublished theses or documents and poster abstracts were excluded. A total of 272 papers were selected and reviewed in their entirety. Articles were excluded based on content listed in Figure 2.1. All literature found was evaluated for relevance to the purpose of the integrative review.

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Literature focusing on chronic conditions or length of stay was excluded from the review, because the focus was not to evaluate risk factors, only the effect of having a cardiac condition in addition to co-morbidity or the impact on length of stay associated with a pressure injury in a cardiac patient. Other articles excluded focused on: urinary incontinence, pressure ulcer preventive surfaces, devices to monitor pressure, mental illness, limb circulation after vein harvesting, device related PU's, and patient-nurse ratio or staffing. These articles did not focus on risk factors specific to cardiac patients.

Full-text articles were related to the cardiac population and pressure injury or related skin problems. Articles omitted included mixed critical care populations (medical-surgical or mixed patient populations). Papers were excluded if they did not focus primarily on cardiac patients' and pressure injuries that developed during a hospital admission, if the main goal was to describe risk assessment, preventative therapies, affected limb after coronary artery bypass graft surgery, pressure injury as a chronic condition, staffing, or device related pressure injuries (Figure 2.1).

Data Evaluation

Literature was critically appraised and evaluated for the following items: clearly written purpose or aim of the study, description of the data collection methods, the study examines the population relevant to the aim of the IR, clinical significance, analysis methods are clearly reported, and both results and conclusions are described.

The final review resulted in six quantitative articles that were selected for further evaluation and analysis. The studies included were retrospective or prospective descriptive studies, one literature review, and one group comparison study. A theoretical framework guided one study. Quantitative articles were coded according to criteria relevant to this review: methodological or theoretical rigor and data relevance on a 2-point scale, 0 was assigned as a

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low score and 2 was assigned as the highest.⁸ Study designs with small sample sizes were rated with a lower score (less than 1.5). Studies presenting a clear research question and a theoretical framework were rated with a higher score (1.6 -2.0). Studies with low scores contributed less to the final results based on findings alone. The remaining studies contributed to the final analysis with scores ranging from 1.5-1.8.

Data Analysis

Six research studies discussed risk factors in cardiac patients and were reviewed and analyzed using Whitemore and Knafl (2005) approach. The steps used in this approach consisted of: (1) extracting data from primary sources based upon the characteristics, pressure injury and cardiac patients; (2) selecting significant risk factors from the data; (3) similar data categorized and grouped together; (4) reviewing primary sources and verification of relevant data. The specific data that was synthesized were the risk factors that were evaluated and could potentially contribute to pressure ulcer development in cardiac patients.

Results

The six studies that were selected were published from 1989-2015. Authors of the selected studies were primarily nurses; some studies had additional members for statistical support. The sample populations included participants from ages 0-86 years of age; three studies included patient under the age of 21 (Chen, Shen, Xu, Zhang, & Wu, 2015; Neidig, Kleiber, & Oppliger, 1989; Shen, Chen, Xu, Zhang, & Wu, 2015). One study discussed ethnic background with 91% of participants being Caucasian (Papantonio, Wallop, & Kolodner, 1994). In the selected studies males were equal to or greater than fifty-five percent of the participants. Disease categories were discussed and identified in two articles: congenital heart disease; valvular disease; coronary heart disease; macrovascular disease; and others (Chen et al., 2015; Shen et al.,

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2015). Across the studies, data collection occurred by assessing the patient or reviewing medical records.

The literature search returned articles relevant to the cardiac population; however, only three of six articles included both pediatric and congenital heart disease (Chen et al., 2015; Neidig et al., 1989; Shen et al., 2015). Neidig et al. (1989) was included in the review, despite the length of time (27 years) since publication. Due to the limited availability of literature, adult cardiac patient data were included. There are similarities between operative techniques in managing both adult and pediatric cardiac patients such as cardiopulmonary bypass and hypothermia. In addition to medical treatment modalities, physical effects of heart failure to the body can be managed in a similar manner. Pediatric cardiac patients experience surgeries related to aortic reconstruction with coronary involvement, like adults. To better understand associated risk factors, it is essential to evaluate the adult literature to guide future pediatric cardiac research.

Defining Risk Factors Associated with Cardiac Disease

The literature specific to cardiac patients was reviewed and evaluated. The articles returned in the search consisted of patients who had undergone cardiac surgery. It was not the intent to extract articles that only pertained to surgery; rather this is what the literature review provided. There was no literature returned that evaluated medical cardiac patients who were possibly experiencing heart failure. Themes were extracted from the literature of those whom had cardiac surgery. Feuchtinger, Halfens, and Dassen (2005) categorized critical points for pressure ulcer development into categories (preoperative, perioperative, and postoperative). The variables obtained from this review were placed into one of three categories related to patients undergoing cardiac surgery: pre-operative, intra-operative, and post-operative phases. Significant

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and insignificant risk factors were reported identified and included both because findings were inconsistent among the evaluated literature (Table 2.1).

Pre-operative

Pre-operative variables that were insignificant were associated with patient demographic information, co-morbidity, and previously diagnosed morbidity. Demographic variables insignificant among studies were age (Lewicki, Mion, Splane, Samstag, & Secic, 1997) and gender (Chen et al., 2015; Lewicki et al., 1997; Shen et al., 2015). Insignificant co-morbidities identified were preexisting respiratory disease, body mass index, and peripheral vascular disease. Patients transferred from another institution were not at an increased risk (Papantonio et al., 1994). The number of days spent in the hospital prior to surgery was not related to pressure ulcers, but the authors did not describe the patients' clinical condition (Lewicki et al., 1997; Papantonio et al., 1994).

Pre-operative variables measured that were significant varied among the reviewed literature. The variables included were demographic characteristics, laboratory values, and disease associated co-morbidity. Demographic information that was collected across the studies that were found to be significant were age (Feuchtinger et al., 2005; Papantonio et al., 1994; Shen et al., 2015) and gender (Papantonio et al., 1994). Patient weight was also a significant factor (Shen et al., 2015). Neidig et al. (1989) found both height and weight to be significant, which can be attributed to disproportionate head size that is developmentally normal for the age studied. Pre-operative variables measured that were significant varied among the reviewed literature and did not define the time of laboratory blood collection prior to the surgery. Albumin levels were found to be a significant predictor in acquiring a pressure ulcer (Feuchtinger et al., 2005; Lewicki et al., 1997; Papantonio et al., 1994). Lower hematocrit (Lewicki et al., 1997;

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Papantonio et al., 1994) and hemoglobin levels (Lewicki et al., 1997) were also a contributing factor. Co-morbidities, especially those with diabetes, were likely to acquire a skin injury (Lewicki et al., 1997; Papantonio et al., 1994). Feuchtinger et al. (2005) found that subjects with oxygen supply disease were at a greater risk while Shen et al. (2015) found disease category was a predictor. Diagnoses related to oxygen supply disease were not defined. Chen et al. (2015) and Neidig et al. (1989) further discussed disease category, showing those with congenital heart disease are at the greatest risk of acquiring a pressure ulcer.

Intra-operative

Insignificant intra-operative variables were associated with patient vital signs or the management of the patient's hemodynamic stability. Vital sign measurement included the intra-operative body temperature (Papantonio et al., 1994) and proportion of operating room time when the patient's mean diastolic blood pressure was less than 60mmHg (Lewicki et al., 1997). Intra-operative patient care included time on ECMO or cardiopulmonary bypass and the use of vasopressor agents (Lewicki et al., 1997; Papantonio et al., 1994; Shen et al., 2015).

Intra-operative variables measured that were significant varied among the literature and were associated with timing, medication, and patient vital signs. Papantonio et al. (1994) found one significant intraoperative variable, those who underwent a combination of procedures or required repeated procedures. During this intraoperative phase patients' temperature (Feuchtinger et al., 2005) and lower perfusion pressures or periods of hypotension were predictive of pressure ulcer development (Feuchtinger et al., 2005; Papantonio et al., 1994). Length of surgery or total time in the operating room was significant (Chen et al., 2015; Feuchtinger et al., 2005; Papantonio et al., 1994; Shen et al., 2015). Those receiving corticosteroids during the

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intraoperative period were found to have a significant risk of acquiring a pressure ulcer (Chen et al., 2015; Shen et al., 2015).

Post-operative

Post-operative risk factors that were found to be insignificant included those associated with medications: vasoactive agents, (Lewicki et al., 1997; Shen et al., 2015) anesthetic and sedative agents, and corticosteroids (Lewicki et al., 1997). Papantonio et al. (1994) found both post-operative agents and total length of hypothermia blanket time or temperature setting to be insignificant.

During the postoperative period, significant risk factors associated with acquiring a pressure ulcer included mobility, equipment, and body temperature. Those who were unable to be turned due to hemodynamic instability (Feuchtinger et al., 2005), length of intubation (Neidig et al., 1989), decreased level of activity (Lewicki et al., 1997), and overall length of stay (Neidig et al., 1989) developed a pressure ulcer. An additional factor associated with immobility was the presence of equipment that was necessary to sustain life (Lewicki et al., 1997). Lastly, Lewicki et al. (1997) discovered that those patients whom had a difference in time required to return to their preoperative baseline body temperature acquired a pressure ulcer.

Discussion

The purpose of this review was to identify risk factors associated with the development of pressure injuries in cardiac patients and to use these findings to guide future research. Significant risk factors were found among the themes of pre-operative, intraoperative, and postoperative, but were also inconsistent (Table 2.2). Papantonio et al. (1994) limited the study to the evaluation of sacral ulcers. Despite the one hundred fifty-seven pressure ulcers confirmed across the included literature, there is still an insufficient amount of research and larger sample sizes are needed.

Significance of the Study

Cardiac patients have unique risk factors associated with the physiologic effects of abnormal heart function. Since they are likely at increased risk for developing pressure injury during hospitalization, health care providers must change prevention practices. Adult and general pediatric skin care bundles warrant evaluation and refinement to enhance their specificity for pediatric cardiac patients. Considerations must include evidence-based tiered protocols that include prevention plans of care, frequent turning and use of specialty surfaces that are tailored to align pressure redistribution qualities with altered perfusion and hemodynamic status. Advanced technologies are associated with multiple medical devices, a newer and necessary focus for pressure injury prevention in children. Head-to-toe skin assessment should be scheduled and collaborative, inclusive of certified wound ostomy nurses. Lastly, product cost (e.g., fluidized positioners) should be conscientiously weighed against the harm, pain and disfigurement of pressure injury.

Limitations

Although the studies in the review identified the purpose of their research, only one acknowledged the use of a theoretical framework to guide the selection of variables to evaluate pressure ulcers (Feuchtinger et al., 2005). Ethnicity was seldom discussed in the studies and could potentially have offered insight regarding differences among groups with skin integrity and color, associated with assessment (Lewicki et al., 1997; Shen et al., 2015). Few research articles discussed the potential difficulties in detecting Stage I pressure ulcers in patients with dark skin tones (Chen et al., 2015; Papantonio et al., 1994).

The literature did not provide specific definitions or explanations describing why the significant variables could be associated with pressure ulcer development (Chen et al., 2015;

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Feuchtinger et al., 2005; Papantonio et al., 1994; Shen et al., 2015). Lewicki et al. (1997) provided definitions for selected risk factor variables and the role-played in affecting skin integrity; however, information was limited. Neidig et al. (1989) discussed the lack in frequent turning to avoid pressure injury, describing that patients could not be turned until hemodynamic and respiratory stability were achieved. Risk factors associated with pressure ulcer development need to be further defined to better understand the pathogenesis.

Conclusions

Pressure injuries are a problem both health care providers and patients face. The prevention of a pressure ulcer can be difficult because the epidemiology of pressure varies across clinical settings (The Joint Commission, 2016). Pressure injury research in the congenital heart disease population is needed to identify risk factors associated with their clinical condition to improve care.

Framework to Guide Research

The National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel (NPUAP/EPUAP) proposed a conceptual framework, originating in 2009, on pressure ulcer development that includes biomechanical, physiological, and epidemiological evidence (Coleman et al., 2014). This framework was developed to capture factors influencing the development of a patient's pressure ulcer at the local area and systemically. This framework could help capture those biomechanical and physiological factors that are associated with the development of pressure ulcers in congenital heart patients while recognizing individual susceptibility. In addition, risk factors that are felt to be important but lacking confirmatory research are included. In the original framework risk factors were placed in one of two categories, mechanical boundary conditions and susceptibility and tolerance of the individual,

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and further developed by mapping risk factors based on its relationship to the development of a pressure injury. The most recent changes identified causative factors, divided into groups (direct casual and key indirect casual factors), and identified relationships between the factors and pressure injury development. Direct casual factors directly impact the outcome (i.e. Pressure injury). Key indirect casual factors category was added in the most recent change to the framework, dividing indirect casual factors further, based on scientific evidence. A limitation to this framework is the factors and their relation to the anatomical site of the pressure injury. It is recognized that casual factors could have played more than one role in a pathway and this framework did not include varying parameters of risk factors (e.g. mobility, nutrition cal/kg/day). Variations in parameters may play a role in mechanical and individual risk factors and may put patients at a greater risk. This conceptual framework recognizes this importance and the uncertainty of specific mechanisms related to perfusion and consideration for individual susceptibility. For these reasons, the NPUAP/EPUAP new pressure ulcer conceptual framework will be used to guide this research. In addition to risk factors identified in the framework, other factors identified in the literature review will be added. Risk factors from the literature review were identified as either direct or indirect casual factors and placed in either the mechanical boundary or individual susceptibility categories.

(*=Factors identified in the NPUAP/EPUAP framework)

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Mechanical Boundary Conditions

Direct Casual Factors

*Immobility

Activity

Indirect Casual Factors

*Poor Sensory perception and response

Individual Susceptibility and Tolerance

Direct Casual Factors

*Skin/PU Status

*Poor Perfusion

Tissue Perfusion and Oxygenation During ICU Admission

Tissue Perfusion and Oxygenation During Surgical Procedure

Weight

Body Mass Index

Key Indirect Casual Factors

*Diabetes

*Moisture

*Nutrition

*Low Albumin

Other Potential Indirect Casual Factors

*Older Age

*Medication (Anticoagulant or Steroids)

*Pitting Edema

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*Chronic Wound

*Infection

*Acute Illness

*Raised Body Temperature

Operating Room Temperature

Other Risk Factors in the Literature Review

Cardiac Disease Category

Sex

Comorbidity

Length of surgery

Length of time in operating room

Length of time on cardiopulmonary bypass

Length of time on ECMO

Oxygen Supply Disease

Peripheral Vascular Disease

Pre-existing Respiratory Disease

Pressure Injury (add location?)

Repeated procedures or combination of more than one procedure

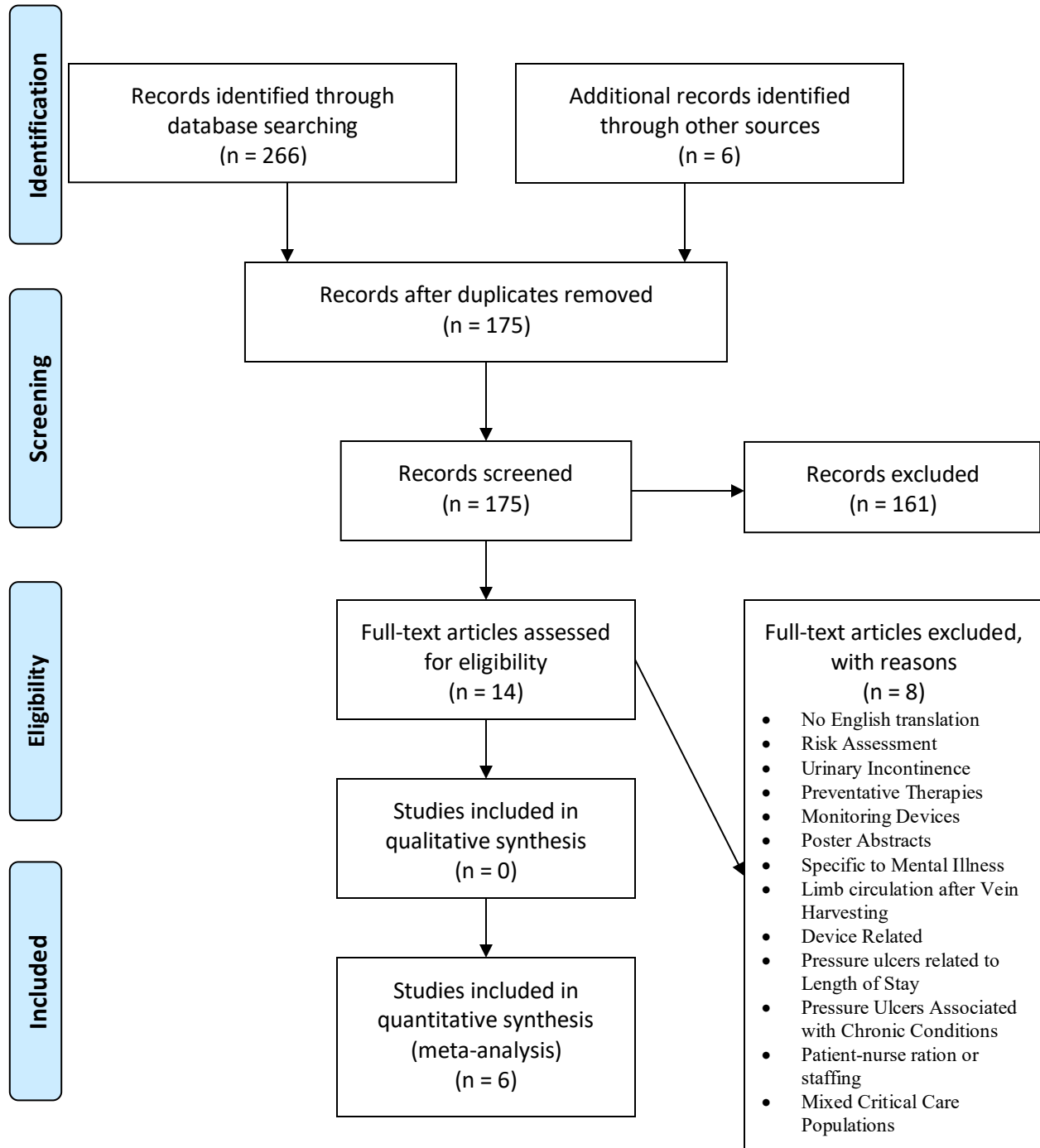
Surgery

Transferred from another institution

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Figure 2.1

PRISMA Flow Diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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Table 2.1

Quantitative Research Results

Author(s)	Purpose and Design	Sample	Findings	Limitations	Data Evaluation
Chen, Shen, Xu, Zhang, Wu (2015)	Examine the relationship between perioperative corticosteroids administration and the incidence of pressure ulcers in cardiovascular surgical patients. Retrospective design	286 patients	SRPU was significantly higher in the group receiving corticosteroids, compared to those who did not receive corticosteroid (43.8%)	Secondary Analysis, retrospective	0.5 Low quality Research P
Feuchtinger, Halfens, Dassen (2005)	Examination of literature to identify risk factors related to patients undergoing cardiac surgery	6 studies evaluated	Risk Factors were summed into three categories: preoperative, perioperative, and postoperative	Available Literature had varying samples sizes, definitions, and sampling procedures	1.8 Medium quality Research T, R
Lewicki, Mion, Splane, Samstag, Secic (1997)	Examination of pre, intra, and postoperative factors associated with the development of PU's in patients	337 patients	16 of 337 patients developed a PU in the post-op period. Significant pre-op (Incidence in	Limited to one center, small number of patients with PU	1.5 Medium quality Research P

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	undergoing cardiac surgery.			study was lower than the previous two years, Hawthorne effect)	
	Prospective descriptive study design.				
Neidig, Kleiber, Oppliger (1989)	To identify risk factors specific to CHD population	59 patients	Age, type of CHD, length of intubation, and duration of stay were significant	Small sample, excluded those who did not survive	1 Low quality Research P
				Missing or unusable data, small sample size	
Papantonio, Wallop, Kolodner (1994)	To determine the incidence of, and variables related to, the development of sacral ulcers in post-op cardiac surgery patients	136 patients	Significant risk factors found in the pre-and intra-operative periods		1.5 Medium quality P
	Two-month prospective design, convenience sample, frequency analysis				

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Shen, Chen, Xu, Zhang, Wu (2015)	Examine the relationship between the length of surgery and the incidence of pressure ulcers in cardiovascular surgery patients Retrospective analysis Matching/control between with and without surgery related pressure ulcer groups	Included both pediatric and adult patients, total of 286 patients, ages 2-84 years of age	Among 286 pts. 47 had SRPUs (16.4%). Age disease category, corticosteroids were statistically significant between the 2 groups. In 47 pediatric patients 2 developed SRPU's.	Retrospective, inability to access information that cannot be obtained in medical records, small sample size	1.5 Medium quality P
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Note. 0-1 = low quality; 1.1-1.5 = medium quality; 1.6-2 = high quality. SRPU = surgery related pressure ulcer; PU = pressure ulcer. Research: T = theoretical framework used to guide study; P = purpose of study discussed; A = which specific risk factors for pressure ulcer development in the cardiac surgery population are identified in the research literature.

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Table 2.2

Risk Factors Associated with Pressure Ulcer Development

Year, Author	2005, Feuchtinger J, et al.	1997, Lewicki LJ, et al.	1989, Neidig et al.	1994, Papantonio CT, et al.	2015, Shen, WQ, et al.	2015, Chen HL, et al.
Pre-operative	Albumin Level* Older age* Oxygen Supply Disease*	Age Albumin level* Diabetes* Gender Greater comorbidity* Lower hematocrit* Lower hemoglobin* Number of pre-op days spend in the ICU	Age* Sex Congenital Heart Defect* Height Weight	Albumin level* Age* Body mass Diabetes* Gender* Hematocrit* Number of days in hospital prior to surgery Transferred from another institution Peripheral vascular disease Pre-existing respiratory disease	Age* Disease category* Gender Weight*	Disease category*

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Intra-operative	High temperature differences* Longer time on OR table* Periods of Hypotension*	Proportion of OR time when patient's mean diastolic blood pressure ≤ 60 mmHg Time on ECMO Time on the OR bed	Cardiopulmonary Bypass Vasoactive Drug Therapy	Total time in OR* ECMO time Temperature Lower perfusion pressures* Repeated procedures or combination of procedures* Vasopressors	Corticosteroids* Length of CPB time Length of surgery* Vasoactive agents	Length of Surgery* Corticosteroids*
Post-operative	Immobility*	Turning activity level* Vasoactive agents Anesthetics Corticosteroids Presence of equipment thought to inhibit mobility* Sedatives	Oxygenation Level Postoperative day Nutritional support Initiated Length of Intubation* Length of Stay*	Postoperative medications Total length of hypothermia blanket time or temperature setting	Vasoactive agents	

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Time required
to return to
pre-operative
body
temperature*

Table 2. Displays both significant and non-significant risk factors associated with pressure ulcer development in cardiac surgical patients.

* = Significant risk factors

Chapter Three

Research Proposal

Introduction/Background

There are an estimated 2.5 million patients per year who acquire a pressure ulcer during their hospital stay (The Institute for Healthcare Improvement, 2014). The annual cost for treating pressure injuries in the United States is approximately \$11 billion (Improvement, 2014). In addition to the financial expense, pain and suffering experienced by patients while treating pressure injuries are immeasurable. Among these patients who acquire pressure injuries are critically ill neonates and children. Across the lifespan, hospitalized patients are evaluated for pressure injury risk development using a validated tool such as the Braden or Norton scales. While experts such as The National Pressure Ulcer Advisory Panel (2014) recommend using a structured approach to risk factor assessment, they do not specify the pressure injury risk assessment tool that should be used. This organization evaluated available expert evidence related to risk factor assessment including: assessment of activity/mobility and skin status, perfusion and oxygenation, nutritional status, increased skin moisture and potential impacts related to increased body temperature, advanced age, sensory perception, hematological measures and general health status (National Pressure Ulcer Advisory Panel, 2014). The recommendations from National Pressure Ulcer Advisory panel for preventive skin care include: incontinence management, keeping the skin clean and dry, avoid positioning on an area of erythema, protect skin from excessive moisture, and using a skin moisturizer to hydrate skin when necessary (National Pressure Ulcer Advisory Panel, 2014). Interventions can be implemented to prevent pressure ulcers including: adequate nutrition, individualized care plan,

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repositioning and early mobilization, and appropriate support surfaces (National Pressure Ulcer Advisory Panel, 2014).

There are recommendations for special populations (bariatric, critically ill, older adults, operating room, palliative care, pediatrics, and spinal cord injury) to be used within the context of the general prevention guidelines (National Pressure Ulcer Advisory Panel, 2014). There are no specific guidelines or recommendations available for cardiac patients across the lifespan.

While these guidelines and recommendations address basic assessment needs, risk factors, and preventative treatment, further research is needed to define variables associated with pressure injury development in disease specific populations such as neonates and children with congenital heart disease and/or heart failure. Guidelines for pressure injury care and management in pediatrics have been adopted from adult data due to the scarcity of studies from pediatric groups (Bernabe, 2012; Curley, Quigley, et al., 2003; Curley, Razmus, et al., 2003; Quigley & Curley, 1996). In addition, patients with unique conditions such as congenital heart disease will need additional measures taken and special care provided to prevent pressure injury. However, risk factors need to be assessed to better protect these patients.

Purpose and Significance of this Study

Cardiac patients have unique risk factors associated with the pathophysiology of abnormal heart function. Since they are likely at increased risk for developing pressure injury during hospitalization, health care providers must adopt prevention practices according to their unique physiology. Adult and general pediatric skin care bundles warrant evaluation and refinement to enhance their specificity for pediatric cardiac patients. Considerations must include evidence-based tiered protocols that include prevention plans of care, frequent turning and use of specialty surfaces that are tailored to align pressure redistribution qualities with altered perfusion

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and hemodynamic status. Advanced technologies are associated with multiple medical devices, a newer and necessary focus for pressure injury prevention in children. Lastly, product cost (e.g., fluidized positioners) should be conscientiously weighed against the harm, pain and disfigurement of pressure injury.

Methods

Design

This non-experimental, retrospective study will use a convenience sample from hospital-acquired data. The purpose of this study is to identify risk factors associated with pressure injury (PI) development in pediatric patients with congenital heart disease and if those who acquire a PI correlate with CHeSS category score.

Specific Aims:

Aim1: To determine the prevalence of pediatric cardiac ICU patients acquiring a pressure injury

Aim 2: To identify the risk factors associated with pressure injuries in pediatric patients with congenital heart disease

Aim 2a: To identify risk factors associated with pressure injury in pediatric patients with congenital heart disease who underwent cardiac surgery

Aim2b: To determine the association between the prevalence of pressure ulcer and the surgical procedure using CHeSS (Congenial Heart Surgical Stay) categories

Aim2c: To determine the association between the prevalence of pressure injury and the complexity of patients' underlying cardiac defects using CHeSS

Aim2d: To determine the association between the prevalence of pressure injury and mortality

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Sample

The sample population for this retrospective study will include patients from the pediatric cardiac intensive care unit (CICU). Patients within this 12 bed CICU are admitted for either medical or surgical cardiac care. Ages range from 0-74 years of age. Medical diagnoses include congenital heart disease, acquired heart disease and cardiomyopathy. Surgical patients were born with a congenital heart defect that required surgical intervention. Either surgical or medical patients may need advanced life supportive measures such as mechanical ventilation, mechanical circulation including extracorporeal membrane oxygenation (ECMO) or ventricular assistant device support. Patients who acquired a pressure injury during their hospitalization in the CICU will be identified through the Quality and Safety Department. Additional patients without pressure injury will be chosen by randomly selecting over a period of time. The period of time will be chosen based on the timeframe the Quality and Safety Department can extract data (it is thought data can be extracted from 2007 – year to date). An estimated sample size needed for power = .80, $\alpha = .05$, and $F = .25$ is 269 subjects (see Figure 3.1).

Inclusion criteria

Participants regardless of their race, cultural or ethnic background, or religion will be used in this study. Inclusion criteria includes: 1) inpatient in the cardiac intensive care unit; 2) 0-18 years of age; 3) acquired a pressure injury during their admission.

Exclusion criteria

1) Patients who are greater than 18 years of age; 2) patients who were not admitted to the Cardiac ICU during their hospitalization.

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Setting

This research study will be conducted using a retrospective convenience sample, Children's Hospital of Pittsburgh of UPMC. This site is part of a large teaching hospital in Southwestern Pennsylvania. Data will be extracted from the patients' medical record.

Data Collection

Data will be collected through medical record review. Patients who had pressure injuries will have medical record numbers provided by the Quality and Safety Department at Children's Hospital of Pittsburgh of UPMC. Collected data will include: age, sex, presence of pressure injury, anticoagulation, body temperature, corticosteroid use, CHeSS categories (Congenital Heart Surgical Stay); tissue perfusion and oxygenation, blood pressure, hemoglobin and hematocrit, albumin level, repeated or combination of procedures, and cardiac surgery. Subjects who developed a pressure injury and had surgery/procedure within 7 days prior will have additional variables collected which include: lowest body temperature during procedure, length of time in operative or procedural room, length of operation or procedure, length of time on cardiopulmonary bypass, tissue perfusion and oxygenation during procedure, lowest mean blood pressure, portion of time mean blood pressure was low, systolic and diastolic blood pressure associated with lowest mean pressure, lowest hemoglobin, hematocrit and pH value. Patients with missing data will be included in the study and the investigator will also code-missing data in the data collection sheet. Patients who do not have a pressures injury will be randomly chosen within the same timeframe as those with pressure injuries and will be collected through the CICU admission records. Linkage codes will be assigned to each subject and stored in a personal folder within the UPMC server. Case report forms will be de-identified and stored separately under lock and key. Data files will be stored on the UPMC server, in a file that is password

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protected. The principal investigator will be responsible for maintaining the safety and security of all research data.

Instruments

No instrument will be used in this study.

Reliability and Validity

Due to the fact there are no survey or measurement instruments being used in the study, there is no reliability and validity evidence to discuss. Yet, in this study the researcher assumes medical record charting is accurate and not limited due to omissions within the patients' chart. The number of available patients will be enough to demonstrate the risk of acquiring a pressure ulcer in the congenital heart disease population.

Institutional Review Board

Institutional Review Board approval will be obtained from both the Institutional Review Board at Duquesne University and the Human Research Protection Office at the University of Pittsburgh. Once approvals are completed, the investigator will acquire patients' medical record numbers from the hospital quality department, who manages and stores data for nursing quality indicators (i.e. patients who developed a pressure injury).

Data Analysis

SPSS Statistics version 25 will be used to analyze data. Participant data will be collected by paper first, then entered into the database, and cleaned in preparation for analysis. The dependent variable for this study is pressure injury (including staging). The independent variables include: anticoagulation, body temperature, corticosteroid use, CHeSS categories (Congenital Heart Surgical Stay), tissue perfusion and oxygenation, blood pressure, hemoglobin and hematocrit, extracorporeal membrane oxygenation, albumin level, repeated or combination of

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procedures, and cardiac surgery. Subjects who developed a pressure injury and had surgery/procedure within 7 days prior will have additional variables collected which include: lowest body temperature during procedure, length of time in operative or procedural room, length of operation or procedure, length of time on cardiopulmonary bypass, tissue perfusion and oxygenation during procedure, lowest mean blood pressure, portion of time mean blood pressure was low, systolic and diastolic blood pressure associated with lowest mean pressure, lowest hemoglobin, hematocrit and pH value. Age and sex will also be collected. Descriptive statistics including the mean, median, and interquartile ranges for continuous variables and counts and percentages for categorical variables will be calculated.

Research Question One

To answer research question one, what risk factors are associated with pressure injury development in pediatric patients with congenital heart disease? Chi-square analysis will be performed to compare risk factors between patients with and without pressure injury.

Research Question Two

To answer research question two, What is the probability of pediatric cardiac ICU patients acquiring a pressure injury based on significant risk factors? Separate Bayes analyses will be used to describe the probability of acquiring a pressure injury based on significant risk factors. For example, what is the probability of acquiring a PI if tissue perfusion and oxygenation is below 90%?

Research Question Three

To answer research question three, Do pediatric cardiac patients who acquire a pressure injury have a higher CHeSS category score?

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Chi-square analysis will be performed to compare mortality and disease category between patients with and without pressure injury.

Research Question Four

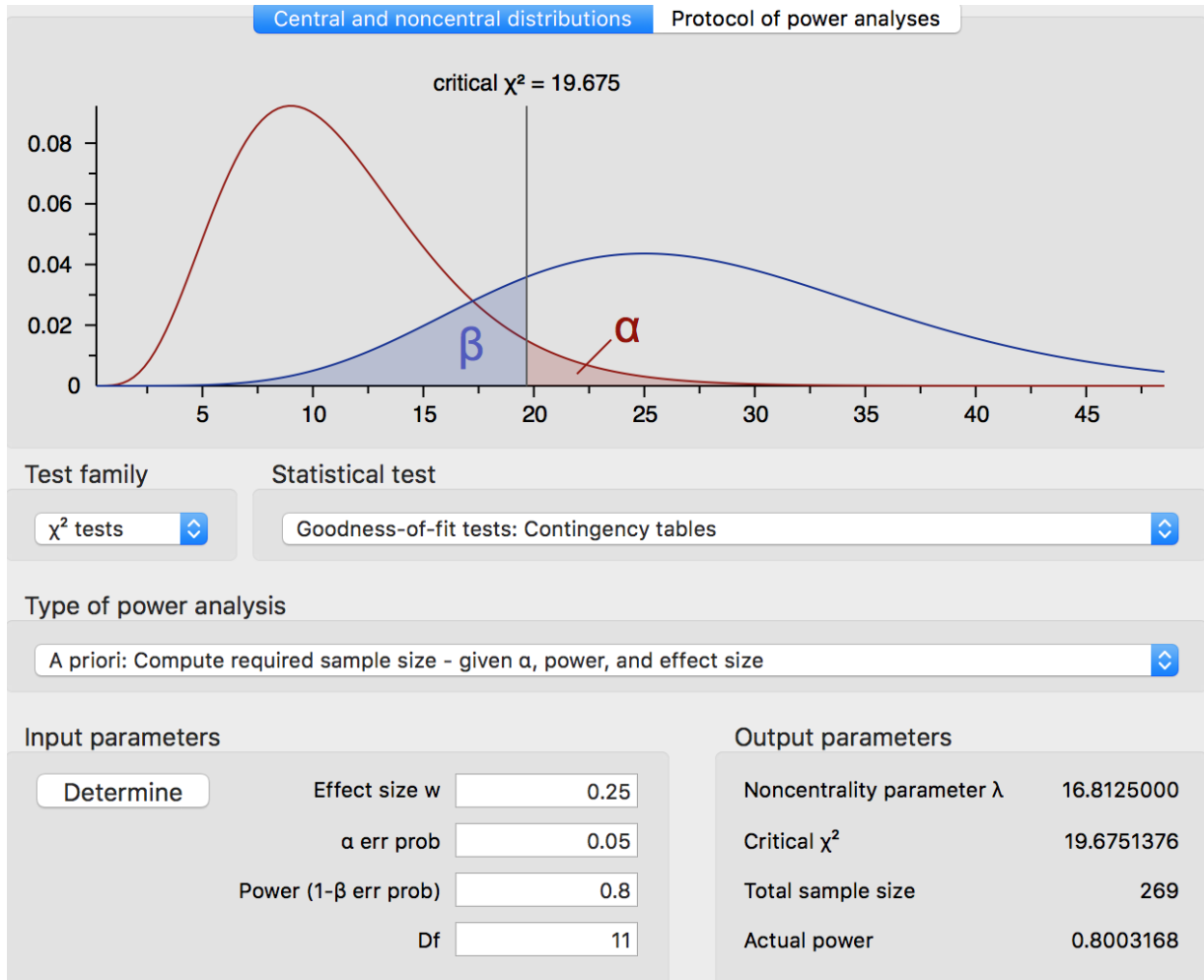
To answer research question four, what risk factors are associated with pressure injury development in pediatric patients with congenital heart disease who have undergone cardiac surgery?

Chi-square analysis will be performed to compare mortality and disease category between patients with and without pressure injury.

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Figure 3.1

Power Analysis



Chapter Four

Risk Factors Associated with Pressure Injury in Pediatric Patients with Congenital Heart Disease

Background

There are an estimated 2.5 million patients per year who acquire a pressure injury during their hospital stay from the report of The Institute for Healthcare Improvement (2014). The annual cost for treating pressure injuries in the United States is approximately \$11 billion (Improvement, 2014). In addition to the financial expense, pain and suffering experienced by patients while treating pressure injuries are immeasurable. Among these patients who acquire pressure injuries are critically ill neonates and children. Interventions can be implemented to prevent pressure ulcers including: adequate nutrition, individualized care plan, repositioning and early mobilization, and appropriate support surfaces (National Pressure Ulcer Advisory Panel, 2014).

Although there are guidelines and recommendations to address basic assessment needs, risk factors, and preventative treatment. The studies to define variables associated with pressure injury development in neonates and children with congenital heart disease and/or heart failure are scarce. Guidelines for pressure injury care and management in pediatrics have been adopted from adult data due to the scarcity of studies from pediatric groups (Bernabe, 2012; Curley, Quigley, et al., 2003; Curley, Razmus, et al., 2003; Quigley & Curley, 1996). Therefore, the purpose of this study is to understand the risk factors and the associated special measures in the delivery of care and unique population of congenital heart disease in children.

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Purpose and Significance of this Study

Cardiac patients have unique risk factors associated with the pathophysiology of abnormal heart function. Since they are likely at increased risk for developing pressure injury during hospitalization, health care providers must adopt prevention practices according to their unique physiology. Adult and general pediatric skin care bundles warrant evaluation and refinement to enhance their specificity for pediatric cardiac patients. Considerations must include evidence-based tiered protocols that include prevention plans of care, frequent turning and use of specialty surfaces that are tailored to align pressure redistribution qualities with altered perfusion and hemodynamic status. Advanced technologies with multiple medical devices improve the survival of these critically ill children in the same token; it makes the necessary of pressure injury prevention in children.

Identification of Risk Factors

Patients with congenital heart diseases or heart failure have unique risk factors associated with pressure injury due to the pathophysiology of a poorly functioning heart or altered anatomy, which, make patients susceptible to pressure injury. These factors include but are not limited to pathological anatomy and low cardiac output, hypoxemia, pharmacologic-related risk, edema, medication inhibiting skin integrity, and extracorporeal membrane oxygenation (ECMO) support. Physiologic differences exist between congenital heart patients and those with normal cardiac anatomy and hemodynamics, affecting adequate perfusion and oxygen delivery/consumption by tissues. Congenital heart defects were excluded in the limited studies that included pediatrics (Curley, Quigley, et al., 2003; Curley, Razmus, et al., 2003; Quigley & Curley, 1996). Congenital heart disease (CHD) patients were excluded from Curley et al.'s study because of chronic hypoxemia and the unclear role this plays in pressure injury development (Curley,

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Razmus, et al., 2003). Pediatric cardiac patients were included in Curley et al's study in 2018 to predict pressure injuries with medical devices (Curley et al., 2018). Pressure ulcers are commonly seen in critical care patients because of hemodynamic instability, vasoactive drugs, and devices related to care (The Joint Commission, 2016). Therefore, it is important to understand the etiology of pressure injuries to make changes in prevention practice(s) to prevent future occurrences of pressure injuries.

These articles included both congenital heart diseases and pediatric patients during literature search (Chen et al., 2015; Neidig et al., 1989; Shen et al., 2015). Neidig et al. (1989) was included in the review, despite the length of time (27 years) since publication. Due to the limited availability of literature, adult cardiac patient literature was reviewed. There are similarities between operative techniques in managing both adult and pediatric cardiac patients such as cardiopulmonary bypass and hypothermia. In addition to medical treatment modalities, pathological effects of heart failure to the body can be managed in a similar manner. Pediatric cardiac patients experience surgeries related to aortic reconstruction with coronary involvement, like adults. To better understand associated risk factors, it is essential to evaluate variables in adult literature to guide pediatric cardiac research.

Framework to Guide Research

The National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel (NPUAP/EPUAP) proposed a conceptual framework, originating in 2009, on pressure ulcer development that includes biomechanical, physiological, and epidemiological evidence (Coleman et al., 2014). This framework was developed to capture factors influencing the development of a patient's pressure ulcer at the local area and systemically. This conceptual framework recognizes this importance and the uncertainty of specific mechanisms related to

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perfusion and consideration for individual susceptibility. For these reasons, the NPUAP/EPUAP new pressure ulcer conceptual framework was used to guide this study.

Methods

Design

This non-experimental, retrospective study used a convenience sample from hospital-acquired data. The purpose of this study is to identify risk factors associated with pressure injury (PI) development in pediatric patients with congenital heart disease and if those who acquire a PI correlate with Congenital Heart Surgical Stay (CHeSS) category score. The research questions the study sought to answer were:

- What risk factors are associated with pressure injury development in pediatric patients with congenital heart disease?
- What factors increase the probability of pediatric cardiac ICU patients acquiring a pressure injury based on significant risk factors?
- Do pediatric cardiac patients who acquire a pressure injury have a higher CHeSS category score?
- What risk factors are associated with pressure injury development in pediatric patients with congenital heart disease who have undergone cardiac surgery?

Sample

The sample population for this retrospective study included patients from a pediatric cardiac intensive care unit (CICU). Patients within this 12 bed CICU are admitted for either medical or surgical cardiac care. Ages range from 0-74 years of age. Medical diagnoses include congenital heart disease, acquired heart disease and cardiomyopathy. Surgical patients were born with a congenital heart defect that required surgical intervention. If needed, advanced life

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supportive measures such as mechanical ventilation, mechanical circulations including extracorporeal membrane oxygenation (ECMO) or ventricular assistant device support were provided to the patients during their CICU stay. . Patients who acquired a pressure injury during their hospitalization in the CICU were identified through the Quality and Safety Department. Additional patients without pressure injury were randomly selected between 2011-2018. An estimated sample size for chi-square was calculated using G*Power (Faul, Erdfelder, Lang, & Buchner, 2007) software. The needed subjects for power = .80, $\alpha = .05$, and $F = .25$ is 269 subjects.

Inclusion criteria

Participants regardless of their race, culture, ethnic background, or religion were used in this study. Inclusion criteria includes: 1) inpatient in the cardiac intensive care unit; 2) 0-18 years of age; 3) acquired a pressure injury during their admission or were randomly selected without pressure injury as a control.

Exclusion criteria

1) Patients older than 18 years of age; 2) patients who were not admitted to the Cardiac ICU during their hospitalization.

Setting

This research study was conducted using a retrospective convenience sample. This site is part of a large teaching hospital in Southwestern Pennsylvania. Data was extracted from the subjects' medical record.

Institutional Review Board

Institutional Review Board approval was obtained from both the Institutional Review Board at Duquesne University and the Human Research Protection Office at the University of Pittsburgh (PRO18100179).

Statistical Analysis

SPSS Statistics version 25 was used to analyze data. Chi-square analysis was performed to compare risk factors. Descriptive statistics are provided in Table 4.1. To answer the research questions Chi-square analysis was performed to compare risk factors.

Results

Two hundred sixty-nine participants (male $n= 163$, female $n= 106$) admitted to the Cardiac Intensive Care Unit were included in this study. During the study period, eighty-two patients acquired pressure injuries, sixty-six were included in the study. Ages ranged from 0-227 months with a mean age of 52.1(SD=69.9) months. The remaining two hundred three subjects were selected randomly using random number tables from 3,633 patients.

Risk Factors Associated with Pressure Injury

Results of the analysis, all but two variables of interest (hypoxia and albumin level) were observed to be associated with pressure injury development using the traditional $p \leq .05$ (Table 4.1). Based on the p-values, corticosteroids and anticoagulants appear to be important. Ninety-six patients were prescribed corticosteroids and 81% of those subjects ($n=54$) acquired a pressure injury. Corticosteroid use and acquiring a pressure injury during hospitalization had a Phi value of 0.55 a Pearson $\chi^2 (N = 269) = 81.08, df= 1, p < .001$ and odds ratio = 17.25. Anticoagulation was prescribed in 107 subjects, with 47(43.9%) acquiring a pressure injury (71% of subjects with a pressure injury were on anticoagulants). Subjects' medical records were evaluated for the use

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of medication for purposes of anticoagulation (Heparin, Coumadin, Lovenox). Anticoagulation use and acquiring a pressure injury during hospitalization had a Phi value of 0.36, a Pearson χ^2 ($N = 269$) = 36.07, $df = 1$, $p < .001$ and odds ratio = 5.89. Descriptive statistics were used to describe factors associated with subjects who underwent cardiac surgery in Table 4.2.

Risk for Acquiring a Pressure Injury

Logistic Regression analysis was used to predict the probability that a participant would acquire a pressure injury. The predictor variables included, transplant and those with the highest odds ratios, anticoagulation and corticosteroid, which creates best scenario for the logistic model. The overall predictive model for acquiring a pressure injury in the presence of prescribed anticoagulant and corticosteroid had an OR 3.25, 95% CI [1.58-6.65] and 9.98, 95% [4.68-21.3] respectively and $p < .001$. Transplant had a reduced probability of being place in the pressure injury group (Table 4.3), OR .80, 95% CI [.68- .95]. The model was able to accurately predict pressure injury for those prescribed both anticoagulant(s) and corticosteroid(s) 84% of the time.

Reason for Admission, Prevalence of Pressure Injury and Mortality

Congenital Heart Surgical Stay (CHeSS) category (Figure 1.1) was used to classify disease category, the purpose of the tool is to predict extended cardiac ICU length of stay. Chi square analysis was used to analyze whether CHeSS category (Table 4.4), in patients with congenital heart disease is associated in the development of pressure injuries and if mortality was associated with admission reason. CHeSS category and acquiring a pressure injury during hospitalization had a Phi value of 0.36 a Pearson χ^2 ($N = 205$) = 27.14, $df = 4$, $p < .001$. Categories not associated with CHeSS (Transplant, Ventricular Assist Device, Medical Admission) had a Phi value of 0.73, a Pearson χ^2 ($N = 64$) = 34.69, $df = 2$, $p = .000$. Mortality was

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not associated with admission reason, but significantly associated with pressure injury with a Phi value of 0.29, a Pearson $\chi^2 (N = 269) = 23.69, df = 1, p < .001$.

Discussion

This results of the study show subjects most likely to acquire a pressure injury are those who are admitted and who receive corticosteroid and anticoagulant treatment during their in admission. Consistent with previously published adult studies, Lower hematocrit (Lewicki et al., 1997; Papantonio et al., 1994) and hemoglobin levels (Lewicki et al., 1997), those who underwent a combination of procedures or required repeated procedures (Papantonio et al., 1994) contribute to pressure injury development. Sex was insignificant in two studies including congenital heart defects (Neidig et al., 1989; Shen et al. 2015). Hypotension, admission reason, and temperature were significant in this study and no literature demonstrates the significance of these variables the cardiac intensive care setting. There is no study that discusses pressure injury prevalence among pediatric transplant patients. Neidig et al. (1989) discussed only Atrial Septal Defect and Ventricular Septal Defects as being included. Curley et. al (2018) used RACHS-1 category to describe cardiac disease severity in a study, findings compared to this study indicate that those with increased severity (RACHES-1, ≥ 3 ; CHeSS 5) are at a higher risk.

Study findings inconsistent with previous studies included steroids, albumin levels, and hypoxia. The study demonstrated steroids as a risk factor while previous studies demonstrated insignificance with corticosteroids (Lewicki et al., 1997); however, those receiving corticosteroids during the perioperative period were found to have a significant risk of acquiring a pressure injury in adult patients (Chen et al., 2015; Shen et al., 2015). Albumin levels were found to be a significant predictor in acquiring a pressure injury among adult cardiac patients (Feuchtinger et al., 2005; Lewicki et al., 1997; Papantonio et al., 1994) and insignificant in the

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CHD population. Feuchtinger et al. (2005) found that subjects with oxygen supply disease were at a greater risk while Shen et al. (2015) found disease category was a predictor. Diagnoses related to oxygen supply disease were not defined. Chen et al. (2015) and Neidig et al. (1989) further discussed disease category, showing those with congenital heart disease are at the greatest risk of acquiring a pressure injury. The findings in this study showed that hypoxia was not associated with pressure injury development. Yuska (2010) suggests anticoagulants slow or affect wound healing; however, no study has confirmed what role anticoagulation therapy plays, if any, in pressure injury development. Galvan (1996) discusses therapeutic advantages of heparin for wound healing, but lack in research of heparin use in the presence of ischemia and vascular problems.

Descriptive statistics were provided in our study related to patients who underwent cardiac surgery and acquired a pressure injury within seven days after surgery. The adult cardiac surgery literature provides conflicting evidence related to temperature, blood pressure and timing. During this intraoperative phase patients' temperature (Feuchtinger et al., 2005) and lower perfusion pressures or periods of hypotension were predictive of pressure ulcer development (Feuchtinger et al., 2005; Papantonio et al., 1994). In our study the mean temperature was thirty-one degrees Celsius ($SD = 5.4$) and mean blood pressure ($M = 32$; $SD = 13.5$). Length of surgery or total time in the operating room was significant (Chen et al., 2015; Feuchtinger et al., 2005; Papantonio et al., 1994; Shen et al., 2015). The mean length of surgery in the population studied was 286 minutes ($SD = 164$) and total time in operating room was 376 minutes ($SD = 189$). Time on ECMO or cardiopulmonary bypass was reported as insignificant in adult cardiac surgery (Lewicki et al., 1997; Papantonio et al., 1994; Shen et al., 2015), our cardiopulmonary bypass time had mean of 167 minutes ($SD = 83$) While both pediatric

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congenital heart disease and adult cardiac patients undergo cardiac surgical procedures, it is difficult to draw conclusions between the populations because of the vast differences in surgeries alone.

Limitations

A retrospective study does not permit characterization of the study cohort as precisely and accurately as a well-executed prospective study. We depended on the data recorded by physicians and nurses who were responsible for care. This study was limited to one freestanding tertiary urban care center. A convenience sample will be used based on a defined period and may also include a limited number of subjects in each group. Since this study data is from a limited period of time, there could be limitations the researcher is unaware of such as changes in practice, products, or specialty beds available.

Conclusions

Pressure injuries are a significant problem for health care providers, patients and families. Despite national attention, prevention of a pressure injury can be difficult because the epidemiology of pressure varies across clinical settings (The Joint Commission, 2016). Our study demonstrated there are significant increased risk factors among congenital heart disease patients in children and the use of steroids and anticoagulation.

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Table 4.1

Variables Evaluated for Association in Development of Pressure Injury

Variables	Pressure Injury (N=66)	No Pressure Injury (N=203)	<i>df/P</i>	OR
Albumin Level (N=179)	59 (89.3)	120 (59.1)	1/. 79	1.08 <i>M</i> = 3.2 <i>SD</i> = .69
Anemia Hgb (N=261)	65 (98.4)	196 (96.5)	1/< .001	3.0 <i>M</i> = 11.2 <i>SD</i> = 2.2
Hct (N=261)	65 (98.4)	196 (96.5)	1/< .001	2.72 <i>M</i> = 33.4 <i>SD</i> = 6.9
Anticoagulant (N=107)	47 (71.2)	60 (29.5)	1/<. 001	5.89
Hypotension (N=191)	38 (57.5)	153 (80)	1/. 006	0.44
Hypoxia (N=66)	20 (30.3)	46 (22.6)	1/.96	1.01

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Multiple Procedures (N=45)	19 (68.2)	26 (12.8)	1/.003	2.75
Sex			1/.042	1.85
Male (N=163)	47 (71.2)	116 (57.1)		
Female (N=106)	19 (28.8)	87 (42.8)		
Steroids (N=96)	54 (81.8)	42 (20.6)	1/<.001	17.25
Surgery (N=198)	37 (56.1)	161 (79.3)	1/<.001	0.33
Temperature (N=133)	19 (28.8)	114 (65.5)	1/<.001	0.316

Abbreviations: Hgb, Hemoglobin; Hct, Hematocrit

Values in second and third columns are number (percentage). Categorical variables are described as number (percentage).

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Table 4.2

Characteristics of patients who underwent cardiac surgery (N = 37)

	M/SD	Median	Mode	Minimum	Maximum
Length of Time in Operation Room (minutes)	376/189	345	67	67	836
Length of Procedure (minutes) (N=35)	286/164	277	143	27	641
Cardiopulmonary Bypass (minutes) (N=29)	167/83	171	185	48	365
Lowest Temperature	31/5.4	33	34.2	17.4	37.4
Lowest Oxygen Saturation	79/16.6	79	100	12	100
Lowest pH	7.28/.1	7.29	7.22	6.9	7.47
Lowest Mean Blood Pressure	32/13.5	29	22	8	66
Lowest Hemoglobin	9.3/2.1	9.2	9.5	6	17
Lowest Hematocrit	27.6/6.3	27	29	19	50

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Table 4.3
Linear model predictors of pressure injury

	<i>b</i>	S.E.	<i>p</i>	Exp(B)/95% CI
Step 3				
Constant	-3.86	.72	.0000	.021
Anticoagulation	1.18	.36	.001	3.25 [1.58-6.65]
Corticosteroids	2.3	.38	.000	9.98 [4.68-21.3]
Transplant	-.21	.08	.011	.80 [.68-.95]

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Table 4.4

CHeSS Category/Admission Reason

Category	Frequency /Pressure Injury	Percent/Percent with PI
CHeSS 1	34/3	12.6/4.5
CHeSS 2	47/0	17.5/0
CHeSS 3	59/11	21.9/16.7
CHeSS 4	31/9	11.5/13.6
CHeSS 5	34/14	12.6/21.2
Transplant	30/21	11.2/31.8
Ventricular Assist Device	7/7	2.6/10.6
Medical Admission	27/1	10/1.5
Total	269/66	100/100

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