Abstract

An Evidence-Based Approach to Percutaneous Coronary Intervention Access

by

Kemi Funlayo Sanni

MSN, Walden University, 2013

BSN, Delaware State University, 2012

Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

Walden University

May 2018

Abstract

Coronary heart disease is a significant cause of mortality and morbidity in the United States; Healthy People 2020 set an objective to reduce the rate of the disease by 20% to the baseline rate of 126 deaths per 100,000 population per year. In the local healthcare setting, heart disease was responsible for a high percentage of mortality and morbidity. To address this, the local site developed a plan to improve outcomes for patients seeking care at the facility. Because the femoral approach to percutaneous coronary intervention (PCI) was used to treat coronary heart conditions at the site and complications were frequent, a quality improvement initiative was begun that included a shift to the use of radial artery PCI. The purpose of this project was to evaluate whether the new approach lowered the complication rates. The project focused question asked how the complication rate of transradial and transfemoral approach to PCI compared. Data from nonrandom aggregate PCI results for 158 adult patients, ages 40-80 years; data from the National Cardiovascular Data Registry; and summarized unit reports were used to compare the transfemoral and transradial outcomes. Two-samples *t* test results indicated the complications were clinically and significantly lower ($p < .01$) with patients who underwent the transradial approach ($n = 82$) compared to those who had the transfemoral approach ($n = 76$). Study results suggest the new initiative using the transradial approach for PCI reduced the complications for patients undergoing PCI at the site. Positive social change is possible as the morbidity and mortality rates were reduced and consumers who need the procedure may experience a lower burden of physical and fiscal cost.

An Evidence-Based Approach to Percutaneous Coronary Intervention Access

by

Kemi Funlayo Sanni

MSN, Walden University, 2013

BSN, Delaware State University, 2012

Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

Walden University

May 2018

Dedication

I dedicated my capstone project to my late father, Chief Solomon Opeolu Shodiya, a retired chief superintendent of marine police for enlightening me on the importance of education.

Acknowledgments

To my daughters, Princess Kudirat Shoda, Princess Zainab Shoda and Princess Fathia Sanni, I appreciate the moral support you ladies showed throughout the program. To the love of my life, Prince Adegboyega Ogunwusi, thank you for being my vision and for your moral support. To my mother, Chief Esther Kehinde Shodiya and my siblings, thank you.

Dr. Janice Long, thank you for your support and guidance throughout the project. Thank you for pushing me and for making me believe in my strength.

Dr. Arvin Gireesh, thanks for your inspirational and professional support in ensuring the smooth completion of the project.

In all, I thank God almighty, without whom my existence would have never been.

Table of Contents

List of Tables

Section 1: Introduction

Introduction

Coronary heart disease is a complication of the heart that negatively impacts its function, and the primary cause of coronary heart disease is atherosclerosis. The National Heart, Lung, and Blood Institute (2017) stated that coronary heart disease is a disease in which plaque-termed atherosclerosis builds up inside the coronary arteries. For diagnosis purposes, a cardiac catheterization may be performed using a catheter to visualize the internal structures of the coronary arteries. The risks are exclusive to a four in 1,000 chance of death. Other risks include dangerous arrhythmia, myocardial infarction, cerebrovascular accident, open heart surgery, pericardiocentesis, intubation, balloon pump or other left ventricular assist devices. Additional risks include infection, bleeding, emergent blood transfusion, temporary or permanent hemodialysis, potential loss of limb, potential vascular injury, and the need for a temporary or permanent pacemaker implantation. In the case a percutaneous coronary intervention (PCI) was indicated, the risks increased to one in 100. The process involved using a catheter to access the coronary arteries by threading through either a radial or a femoral artery to visualize the damaged or occluded arteries.

PCI, also known as coronary angioplasty, is performed under fluoroscopy so that the interventionist can visualize the inside of the vessels to see the location of the plaque and how the blood flows through the coronary arteries. PCI is the procedure also used for the treatment of some coronary artery diseases such as myocardial infarction to restore blood supply to a damaged heart muscle (Roy, 2014). The procedure is nonsurgical and allows

the interventionist to place a stent in the occluded arteries to keep them open. The outcome of the process is to maintain adequate blood flow to the heart to prevent a heart attack. PCI requires the use of contrast dye and radiation to visualize the arteries for easy bypass of the catheter to the affected vessels. To intervene, the cardiologist passed the tube through the radial or femoral arteries and patients are monitored for post procedural complications. After the procedure, complications may include bleeding, blood vessel damage, allergic reaction, loss of limbs, kidney damage, arrhythmias, emergency coronary artery bypass (CABG), restenosis, stroke, and heart attack. While most PCI procedures occur without complications; when complications occur, they can be devastating to the patient and their family. At the project site where the project took place, PCI was primarily through the femoral route.

One out of the five patients seen at the local hospital have coronary artery disease and will likely undergo a PCI before returning to the community. The local hospital had a high admission rate of patients with coronary artery disease who required PCI, and therefore they developed a project to reduce the alarming mortality and morbidity rates. Included in this project was the intent to improve the outcomes related to PCI for individuals who went through the procedure. Patients who undergo the procedure are at risk for complications which may be related to the vascular access used (Mamas et al., 2014). The femoral approach for PCI vascular access had been traditionally used in the past, but the hospital integrated a second method of access; the radial approach.

In summer of 2015, the site began the use of the radial method as a quality improvement initiative. To determine that the quality improvement change to the radial

approach had made a difference in the complication rates for the procedure; this project was designed to evaluate the differences in outcomes between patients who got treatment with PCI by femoral and radial approaches. This section will continue with the explanation of the problem statement, the purpose, the nature of the doctoral project, the significance, and a summary of the section.

Problem Statement

The most prevalent disease in the United States is coronary heart disease. However, there are optional treatment plans available for patients to treat the disease. One Healthy People 2020 objective includes reducing the rate of heart disease by 20% to the baseline rate of 126 deaths per 100,000 population per year (Gillespie, Wigington, & Hong, 2013). The recommendation was that patients with suspected coronary artery disease would undergo a cardiac catheterization which allows the cardiologist to examine the anatomy and physiology of the heart. As a result, hospitalized patients with a suspected coronary artery disease will have cardiac catheterization and a PCI relatively, if indicated.

Traditionally, the femoral access has been the most frequently utilized in a cardiac catheterization procedure. However, most organizations are deviating from the practice to embrace the transradial access approach. In the acute care setting where this project took place, known complications of the femoral procedure include bleeding, blood vessel damage, allergic reaction, arrhythmias, emergency CABG, restenosis, and death. The radial method emerged in the summer of 2015, and only the project site uses the procedure. There was little known about the types of complications that occurred at the

site, and there has been no attempt by anyone to do a quality improvement study on the approach. Therefore, there was a need for further studies to examine the benefits and the complications compared to the femoral approach. This project compared the number of complications that occurred with the femoral approach to the number of complications that occur using the radial approach and will provide the results to the health system where the project took place.

The doctoral project was significant to nursing practice because safety and quality care are essential for all patients. Hence, using the approach that was most effective for preventing complications and reducing morbidity and mortality for patients who undergo PCI became imperative. The purpose of this project was to compare the outcomes of a transradial versus a transfemoral approach of PCI in patients with the acute coronary syndrome and recommend the best method based on the principal results. The project will provide support for the current evidence-based practice in the clinical setting where this project took place. It will also promote the standardization of transradial approach as the optimal treatment for all patients with the acute coronary syndrome and provide a foundation to prepare nurses for caring for patients pre and post procedure.

Purpose

This Doctor of Nursing practice (DNP) project aimed at translating evidence to improve nursing practice. The purpose of this project was to evaluate a quality improvement initiative undertaken at the local clinical site where this project took place. The results of the evaluation will be used to determine if a transradial approach to PCI provides lower post procedural complications.

The gap-in-practice addressed by this project was that in the current practice setting, no documented evaluation of the effectiveness of the transradial approach compared to the transfemoral approach had been performed at the site. There was a need to understand if the newer transradial approach was more efficient than the transfemoral approach to reducing complications of the procedure. The doctoral project can bridge the gap in knowledge by conducting a comprehensive evaluation that can be applied to the practice setting and assist in decisions for the use of either procedure.

Nature of the Doctoral Project

Deidentified secondary data were collected to support the project. The data obtained were from a published report from the National Cardiovascular Data Registry (NCDR) database and an aggregate report from the unit. The data were analyzed to compare the complication rates for both the transfemoral and transradial approach to PCI in the clinical setting.

During the doctoral project, I met with the quality improvement officer to discuss the project and to assure that I could obtain the required data for the analysis. The number of PCIs done through the femoral access six months before the initiation of the transradial method and the number of PCIs done through the radial access six months after were required for the completion of this project. In addition, the record of all the complications that occurred on the unit with both approaches during the time frame were received. These data were the basis of the comparative study. The doctoral project purpose was to evaluate the transradial approach and the transfemoral approach of PCI for

complications; the recommendations will be applied to practice to bridge the gap-in-nursing practice.

Significance

Femoral access has been the most frequently used in cardiac catheterization procedures (Gunarathne, Alahmar & Gershlick, 2016). However, most organizations are deviating from the femoral access practice to embrace the transradial access method. The practice was relatively new, and the need for further studies to examine its benefits and its complications are imperative to nursing practice to improve quality patient care. The project was relevant to nursing practice as nursing staff monitored patients post procedure. The recommendations from the results of the evaluation were incorporated into nursing practices. For this reason, it was relevant to examine the differences between the two methods used at the project site where this project took place.

The stakeholders involved in the project were the cardiologist performing the procedures and the nurses managing the patient upon return to the unit. The nurses report and document all the complications post procedurally on the unit. The DNP student will submit the results to the school for recording and the site for implementation. The potential implications of the project for positive social change are that the project will assist in the determination of the best approach to PCI while avoiding complications. The hope is that patients' quality of life and care outcomes will improve after this quality improvement (QI) project is confirmed to be effective. Improvements may include reduced length of hospitalization and reduced readmissions for complications.

Summary

Gillespie et al. (2013) argued that one in every four deaths in the United States is due to heart disease, and as of 2013, heart disease is still the number one cause of death in the United States. Cardiologists perform a cardiac catheterization for diagnostic purposes to study the heart and the vessels; they continue with PCI, if indicated. PCI involves the use of a percutaneous catheter, contrast dye, radiation, and x-ray to place a stent into the artery to unblock the plaque and keep adequate blood flow to the heart. There are two approaches to the procedure: the traditional transfemoral approach and the transradial approach. Either of the approaches has post procedural complications but to different degrees. The purpose of the capstone project was to evaluate an existing QI project that was developed by the organization. The project compared the two methods in relationship to their complications and used the findings to make necessary recommendations.

Section 2: Background and Context

Introduction

Heart disease is the number one cause of death in the United States (Murphy, Kochanek, Xu, & Arias, 2014). However, the disease is preventable. The goal of Healthy People 2020 is to improve cardiovascular health through prevention, detection, and treatment. Cardiac catheterization had been the diagnostic tool for coronary heart disease, and PCI had been the procedure of choice. The transfemoral approach had been the regular practice in the treatment of coronary syndrome, but the clinical site added transradial approach as an alternative treatment options. The purpose of the DNP project was to evaluate the complication rates between the transfemoral and transradial PCI approaches. The project question asked the following: How do the complications rate of transradial and transfemoral approach to PCI compare? Section 2 will focus on the concepts, models, theories; relevance to practice, local background and context, the role of the DNP student, the role of the project team, and a summary.

Concepts, Models, and Theories

Three conceptual models were explored and applied to design the project. Theoretical frameworks could guide the nurses in the management of patients' post procedural complications upon return to the unit. The project was significant to nursing practice as it helped nurses create interventions to manage the complications depending on the clinical outcomes of the comparison project. It could also guide the interventionist and the **c**ardiac **c**atheterization laboratory staff in understanding the pre-management and intra-management of the patient during the procedure to minimize post procedural

complications. Understanding of organizational dynamics and the process of change are imperative for the development and the promotion of health initiatives (Batras, Duff, & Smith, 2014). The organizational theory has valuable contributions to make in the establishment and understanding of organizational change.

Nursing practice has developed significantly as a unique profession that is relevant to the future of healthcare delivery in the United States. These developments, however, are results of concepts and theories that are imperative in the advancement and diffusion of nursing practice. The diffusion theory and the system theory are the other methods that will be explored and utilized in the DNP capstone project.

Organizational Change Theory

Organizational change theory can be used to identify influential factors to determine change needs and strategies to implement change that could promote the organization, improve practice, and increase patient care outcomes. Organizational science has developed a theoretical framework for the study of how organizations develop organizational capabilities by incorporating new ideas and innovations (Johnson, Riel, Ogbolu, Moen, Brenner, & Iwu, 2014). Transfemoral approach to PCI has been the historical method for treating the acute coronary syndrome. However, the transradial approach is currently trending. Because it is a new approach, nurses on the unit and in the cardiac **c**atheterization laboratory must change their old practice and learn the new process in the management of transradial method. They can create nursing guidelines primarily for managing post cardiac catheterization complications. Lewin's theory of change proposed three-stages of a model of change that required prior learning to be

rejected and relearned. Well known for his group dynamics, group therapy, and social psychology, Lewin implied that once a behavior relates to one's personality, it defines the situation in which one finds oneself. Lewin's theory can lead to an understanding of how change affects the organization. It helps with identification of barriers to successful implementation and is useful for identifying opposing forces that act on human behavior during the modification. Therefore, the use of the theory helps to overcome resistance and leads to acceptance of new practice by nurses and doctors (Sutherland, 2013).

Theory of Diffusion

Transradial access to PCI is a new approach used by various cardiovascular interventionists to treat acute coronary syndrome or coronary artery disease. The interventionist accesses the radial artery by threading the artery with a catheter and the use of contrast and x-ray to visualize and correct the damages in the artery. The theory of diffusion is a theory that highlight the how, why and rates at which new ideas and innovations spread. The method was developed by Everett Rogers as a social science theory to help explain how a new concept gained momentum and why it is worth applying to practice.

Some nearby hospitals have not yet used the new approach. In this project I sought to inform those facilities on the importance of embracing the new approach using evidence generated to support the objectives. In the nursing profession, evidence-based practice encourages the use of best research evidence to support clinical decisions in practice (Gray, Groove, & Sunderland, 2016). Several reports are promoting the use of transradial approach; however, because the practice is new at the project site, research

must be conducted to validate the reports and to generate evidence. The produce evidence will be used as evidence-based to maximize adoption into practice. One theoretical approach to understanding how to proceed with implementation may be achieved using Roger's diffusion theory (Stevens, 2013). He argued that some characteristics of the concept itself may facilitate its adoption.

Diffusion of innovation theory can provide information on how to prevent coronary artery disease. The system has been applied in different fields to enable clinicians to translate new ideas, such as new treatment approach, disease knowledge, or educational strategies into practical applications. For patient outcomes improvement, the theory of diffusion will help transform new knowledge into clinically useful forms, implement the new knowledge, and measure the meaningful impact on performance and health outcomes (Stevens, 2013).

System Theory

A system theory enables clinicians to understand how the system operates. In the context of accessing the radial artery to repair arterial occlusion, the theory allows the provider to understand the structural aspect of the radial artery. Using the system theory as a framework, the clinicians and nurses will understand not only the anatomy and physiology of the radial artery but also will learn the methods to minimize post procedural complications while improving patient care outcomes. It is imperative to understand how the systems work, to affect sustainable change (Cordon, 2013).

Relevance to Practice

The capstone project is relevant to nursing practice as it evaluated an existing quality improvement initiative focused on preventing post procedural complications. Even though the transradial approach for PCI was not new, it had gained momentum in practice (Delacroix et. al, 2013). As the practice was new at the project site, it was relevant to nursing to know the challenges surrounding the method. The transradial and the transfemoral approach are invasive; there are risks including but not limited to stroke, bleeding, death, loss of limbs, and disability. Therefore, it is imperative to understand the complication rate with each of the procedures at the local health setting

Local Background and Context

In 2015, the hospital implemented a quality improvement project, the use of a radial artery for PCI. This improvement sought to reduce the complication rates from femoral access and to make recovery quicker and safer for the patient (Delacroix et al., 2013). There were complications such as hematoma, extended admission, readmission, pseudoaneurysms, bleeding, and death reported from the former approach. However, there was no study or evaluation performed to assess the complications that occurred with the use of the new approach.

The pathogenesis of the condition requiring the above intervention emerged from atherosclerosis that builds up in the human arteries and impedes healthy blood flow to the heart. The results of this distortion lead to acute myocardial infarction or myocardial ischemia as indicated on the electrocardiogram as an ST elevation or depression. With the chronicity of the condition, thrombolytic complications, the scariest of the consequences

of the disease, could occur suddenly and sometimes without warning (Libby, 2013). To diagnose the disease, the doctor performs arteriography to visualize the stenotic state of the artery. In most cases, the recommended treatment is the use of PCI, which involves opening a stenotic or an occluded artery by atherosclerosis plaques by expanding a balloon in the stenotic artery, usually followed by insertion of a stent (Valaker et al., 2017).

During the procedure, the doctor accesses the radial or the femoral site, advancing a rim catheter into the aorta while intermittently performing an angiogram to monitor the catheter as its thread through the arterial wall. The use of contrast (amount differs in both approaches) provides a better picture of the procedure as the doctor advances the catheter (Litmanovich et al, 2014). The patient receives a thrombolytic agent to prevent blood clot formation during the process. The amount of the thrombolytic agent differs with both approaches and can cause post procedural bleeding upon completion of the procedure.

Dr. Ferdinand Kiemeneij of Amsterdam first introduced the transradial PCI (Armeli, 2017). He found the procedure to be safe, efficient, and cost effective. However, it takes specialized training for a physician to be able to perform the procedure without incurring damage to the radial artery.

In a transfemoral approach, a sheath may be applied to the groin site if a hematoma occurs and that may result in prolonged recovery for the patient. Again, once the doctor removes the sheath and the bleeding continues, it may require additional intervention such as the use of a fem stop to decompress the site and halt the bleeding (Batiha et al., 2016). The transradial approach, on the other hand, involves the use of a

transradial band to promote homeostasis, and it is relevant for nursing staff to know about managing any impending or unforeseen complications for patient safety.

Role of the DNP student

The role of the DNP student was to evaluate an existing quality improvement project that was initiated by the organization in 2015. After receiving the Institutional Review Board's (IRB) approval, I collected the deidentified data consisting of complications that had occurred during the six months before beginning the transradial approach and six months after the introduction of the transradial method. I then compared the complications that were reported during each time. Upon review of the documents, I performed a quantitative analysis using *t* test to analyze the difference between the two sets of data. The *t* test is a type of statistical test used to investigate the differences in variable distributions (Kim, 2015). Once completed, I submitted the data and the results to the school chair for approval, and the project site for implementation.

In order to obtain and use the data from the site, I obtained a confidentiality agreement which was to protect the hospital and to comply with Health Information Portability and Accountability Act (HIPAA) regulations. Also, the compliance officer at the facility requested that the student submit a document disclosing the intention for the use of the data and the plan to dispose of after use. The motivation to undertake the project to assist the hospital with evaluation of the new quality improvement practice was clearly explained and the cardiologist and the compliance officer both indicated their support.

Summary

The PCI femoral approach had been the treatment of choice to treat coronary artery disease until the new radial approach began. Since the inception of the new method of PCI, there has been a reduction in complications post procedurally. When the site began using the new approach for PCI, and because the practice was new, it prompted the doctors and the staff to seek evidence to support the continuation of the PCI approach method. The next section will address how the project developed operationally.

Section 3: Collection and Analysis of Evidence

Introduction

Coronary heart disease is among the most prevalent diseases in the United States. Patients with the disease are recommended to undergo cardiac catheterization and a PCI, which allows the cardiologist to examine the anatomy and physiology of the heart. The traditional cardiac catheterization procedure was through the femoral access. However, there were some complications in using the femoral access approach. Hence, most organizations are deviating from the practice to embrace the transradial access approach. This project compared the number of complications that occurred with the femoral approach to the number of complications that occur using the radial approach and will provide the information to the health system where the project took place. Relative to Section 1 and 2, the following section will address the methodology used for the project and, the sources of evidence analyzed in the same context.

Practice-Focused Questions

The local problem leading to the choice of the project was the complication rates witnessed on the unit before the initiation of the quality improvement project. Both approaches posed complications. However, the capstone project compared the reported complications from both methods of PCI and proposed that the newer method would promote patient safety and quality of life. The practice-focused question is the following: How do the complication rates of transradial and transfemoral approaches to PCI compare?

Sources of Evidence

I used the secondary data that was submitted by the project site to the National Cardiovascular Data Registry (NCDR), the unit post procedural reports, and other scholarly studies as evidence to support this project. The other secondary sources were researched using Walden Library to access CINAHL, Medline Plus, and National Library of Medicine National Institute of Health databases. The scope of the search consisted of scholarly journals less than five years and are peer-reviewed.

As previously stated, the data were secured to ensure that only the project manager had access to the information. There were no consents required as no patient identifiers were used. However, once the project was complete, all the documents received were disposed of according to the hospital policy.

Analysis and Synthesis

The project evaluated the current practice for complications and provided evidence for the best practice for standardization. Outlined below are the steps involved in the project.

Contact facility compliance officer: During this process, I contacted the facility compliance officer to submit the requested document and signed the appropriates as mandated. I also submitted a copy of the proposal indicating the intended use of the data, the security of the data and the disposition method after use. The purpose of the confidentiality form was to ensure that the project follows the facility HIPAA laws and practice regarding personal health information disclosure policy. The key to preserving

confidentiality is to allow only authorized individuals to have access to information (Ozair, Jamshed, Sharma, & Aggarwal, 2015).

Receive IRB Approval: IRB approval was applied for and granted. The IRB approval number for the project is 11-03-17-0367448.

Review the data, resources, and literature: It is significant for the quality improvement project to align with the mission of the organization. It is also essential to inform the staff in the care of the patients of the evidence-based research information relating to the transradial and transfemoral approach to PCI. The facility is a small community hospital with a mission to positively impact the community's quality of life through superior health services. The hospital is a level three trauma center and provides care to the patients with cardiac issues. An average of three to eight doctor-heart cases arrive in the emergency department daily, and 50% of the cases end with a PCI. A review of the literature indicated that the radial approach to angiography has become accepted nationwide and internationally due to its minor complications compared to the traditional femoral approach. Several observational and randomized studies to date have shown an association between radial access and reduced risk of bleeding and vascular complications (Rao et al., 2013).

Quantitative analysis: Upon data collection from the facility, I developed a quantitative report analyzing the complications from both approaches. The report included the gender, the type of procedure (radial or femoral PCI), and the reported complications such as hematoma, bleeding, pseudoaneurysms and death. A quantitative method can be used to measure metrics and physiologies (Beyea & Nicoll, 2017).

Analyze the complication rates using received data: Following the IRB approval by Walden University, I proceeded to collect the data and finalized the analysis. The data from the NCDR and the unit included the type of procedure, the type of complications during and post procedure, and the gender of the patients. I compared the type of complications from both methods and reported the less complicated using the two-sample *t* test statistical test.

Report the less complicated method and recommend for practice: The results of the project are crucial to the interventionist as he would like to use the results to understand the outcome of the procedures better. Therefore, the project results will be made available to the facility and the interventionist and decisions regarding more research or adoption will be addressed accordingly.

I used Microsoft Office software and SPSS to run the statistical analysis report that addressed the practice-focused questions. It was the goal of the student to keep the integrity of the received documents and to ensure the confidentiality regulations were observed. However, the product was used to determine which of the approaches met standard of care practice.

Summary

Chapter 3 indicates how I generated evidence to support the project, and how Microsoft Office and SPSS were used to organize the capstone project paper. A *t* test statistical analysis was used to test the differences between the two methods of PCI access. The application of these methods ensured that the project was detailed and

captured all the necessary information for decision making without any bias or presumptions.

Section 4: Findings and Recommendations

Introduction

The local problem in the project was the new vascular access to PCI that the project site initiated, and no evaluation had been completed to evaluate its effectiveness. There had been an increasing number of patients admitted for acute coronary syndrome at the project site, and the interventionist diverged more to the new practice, the transradial access of PCI while the traditional transfemoral access was losing its popularity due to the change. However, there are records of reported complications from both accesses, ranging from bleeding, hematoma, pseudoaneurysms, and death. The capstone project was an evaluation of a quality improvement project to evaluate the two methods for best results in terms of complication rates.

For the nursing profession to provide care to patients who undergo PCI at the site, it was important that they understand the risks that patients who undergo PCI by either vascular approach. They also needed to be prepared to address complications when they arose, prevent them when possible, and recognize when they occur. To prepare a patient for PCI, the nurse is the first healthcare contact that the patient and their family meet and the nurse positioned to provide information on care before and after the procedure.

The practice-focused question was: How do the complication rates of transradial and transfemoral approach to PCI compare? The evidence for the project was obtained from the National Cardiovascular Data Registry (NCDR) by the project site **c**atheterization laboratory director, the post procedural complications report from the unit, and the use of a *t* test statistic for data analysis.

Findings and Implications

Coronary angiogram and cardiac catheterization are the indicated tests for coronary artery disease. As with any invasive procedure, there are some patient-dependent and procedural-related complications that may occur irrespective of the interventionist or the methods used. The complications, however, may be benign or complicated depending on the patient's state of health.

Means, standard deviations, frequencies, and percentages were used to describe the distributions of the variables between transradial (TR) and transfemoral (TF) cases. By using the *t* test for two independent means, the sample size (158) and the method employed in the comparison between the two variables (TR and TF) do not influence the standardized differences. The *t* test was chosen for the studies to enable assessment of the two approaches for statistical differences. Per the report received, there were 76 TF PCI completed six months before initiating transradial PCI. Six months after the initiation, there were 82 transradial PCI completed (Table 1 through Table 3). Excluded in the study are patients with the repeated PCIs.

Table 1

Number of Completed Transfemoral PCI Prior to QI Project Implementation (N-76)

Six months of completed transfemoral PCI		
Month	Male	Female
January	6	4
February	19	2
March	9	3
April	8	4
May	7	5
June	7	2
Total	56	20

Table 2

Number of Completed Transradial PCI Post QI Project Implementation (N-82)

Six months of completed transradial PCI		
Month	Male	Female
July	8	3
August	6	1
September	7	2
October	8	3
November	16	9
December	10	9
Total	55	27

Table 3

Number of Complications between Femoral and Radial methods.

Report of Both Access Complications		
Complications	Femoral	Radial
Bleeding	10	2
Hematoma	12	1
Pseudoaneurysms	10	0
Death	1	0
Total	33	3

Table 4

Statistical Analysis of both methods complication rates.

Report of Both Access Complications				
PCI Methods	Bleeding	Death	Hematoma	Pseudoaneurysms
Transfemoral	10	1	12	10
Transradial	2	0	1	0
Total	12	1	13	10

$t = 3.00626$ $p = .011907$

Descriptive statistics presented above, show the result of the *t* test statistically significant at the $p < .05$ level (Table 4) indicating a significant difference between the femoral and transradial access PCI in rates of complications post procedurally. This is important to nursing practice as it is our goal that we provide quality care to every patient and improve their quality of life.

According to the above tables, there were 76 transfemoral PCI completed before the QI initiative, and of the 76, there were 33 reported complications which are 44.3% (Table 3). Relatively, there were 82 transradial completed post QI initiative, and there were three complications reported which is 3.56% (Table 3).

The unanticipated limitations or outcomes and their potential impact on the findings were that the volume of anticoagulants and contrast used, the time of radiation exposure during the procedure which varies by the access site used and the time spent on each case contributed to the types of complications experienced post procedurally. The

more anticoagulants used, the more patients are predisposed to bleeding and hematoma (Fox, 2013).

Recommendations

The project site still uses transfemoral access occasionally, and the objective of this capstone project is for a zero-complication rate with the transradial access. Therefore, it is imperative to recommend the following guidelines to prepare nurses in managing posed post procedural complications.

- Bleeding: Assess pressure dressing for oozing or bleeding from the site and mark the size for further assessment
- Hematoma: Assess the site for surrounding tissue swelling, arrhythmias, and
- mark the size
- Infection: Monitor site for heat, redness, and pain (the hallmarks of infection process)
- Pseudoaneurysms: Nurses should apply compression for at least four minutes until no pulses are felt and should be repeated five minutes after to manage the condition. Multiple episodes of compression for a few days or weeks may be required to manage pseudoaneurysms. Patient may also have a fever missed work days and potentially lower stress and lost cost (Mamas et al., 2014).

The potential implication for a positive social change is for nurses to provide quality care that will enhance the life of every patient cared for. Patient should be able to have quality and productive life after their procedures and be able to contribute the welfare of their family and their community.

Strengths and Limitations of the Project

The strength of the project was the sample size of the cases completed within the timeframe and the hospital allowing the project to take place. The hospital staff who contributed to the project were supportive and provided the required resources for the successful completion of the project.

The facility does not have an IRB, and no research had been done previously to evaluate the project therefore, this project may encourage the facility leaders to allow staff in graduate school to conduct more quality improvement projects that can benefit the facility.

Section 5: Dissemination Plan

The role of the DNP student was to conduct the capstone project and submit to the facility for implementation. The findings will be presented directly the interventionist, who oversees the interventions in the **c**atheterization laboratory. I will also present to the cardiologists at the facility, the **c**atheterization laboratory nurses, and the nurses on the unit. It is important that nurses are informed about procedures conducted on the unit and can provide support and education to patients who are undergoing the procedures. The cardiologists may also share the information with other neighboring hospitals that are yet to adopt the transradial method to PCI.

Analysis of Self

I currently work at the project site as one of the nurses on the unit in collaboration with the cardiac catheterization laboratory nurses. Our primary duties are to prepare the patients for the procedure and manage their condition post procedurally. We reported every complication patients experienced to the charge nurse on the unit and to the interventionist. I recognized the need to have information on the types of procedures that patients are undergoing at the site and that I need to be informed and to keep up with the evidence in the literature that can improve practice in caring for patients who come to the unit for PCI. I am working with the clinical personnel to create practice guidelines to provide better care to the community and improve patient care outcomes for those undergoing PCI.

Summary

In conclusion, the project reinforced the new approach to PCI by presenting the lower complication rates for patients who undergo the PCI transradial approach. By completing this project, I learned to evaluate a quality improvement project and the steps involved in documentation of it.

This project and the findings from it will assist the unit nurses in the efficient management of patients with transradial PCI and thereby improve care outcomes.

References

Armeli, A. (2017). Father of transradial intervention. *Cardiac Intervention.* Retrieved February 26, 2018 from https://www.merit.com/father-of-transradial.

Batiha, A., Abu-Shaikha, H. A., Alhalaiqa, F. N., Jarrad, R. A., Ramadan, H. J., (2016). Predictors of complications after sheath removal post transfemoral percutaneous coronary intervention. *Journal of Online Nursing,* 6:497-504. doi:10.4236/ojn.2016.66052

Batras, D., Duff, C., & Smith, B. J. (2014). Organizational change theory: Implications for health promotion practice. *Health Promotion International*, *32*(1), 233-241. https//doi.org/10.1093/heapro/dau098

Beyea, S. C., & Nicoll, L. H. (2017). Qualitative and quantitative approaches to nursing research. *Association of periOperative Registered Nurses Journal, 66*(2), 323-325. doi:http://dx.doi.org/10.1016/S0001-2092(06)62803-3

Cordon, C. P. (2013). System theories: an overview of various system theories and its application in healthcare. *American Journal of Systems Science, 2*(1): 13-22. doi:10:5923/j.ajss.20130201.03

Delacroix, S., Psaltis, P. J., Worthley, M. I., & Worthley, S. G. (2013). Transradial access for ACS and STEMI: A literature review revealing why transradial access should be the standard for coronary imaging and interventions. *Journal of Cardiovascular Interventions Today,* July/August 2013.

Fox, K. (2013). Dual or single antiplatelet therapy with anticoagulation? *Lancet*, *381*(9872), 1080-1081. doi.org/10.1016/S0140-6736(13)60054-9

Gray, J. R., Grove, S. K., & Sutherland, S. (2016). The practice of nursing research: appraisal, synthesis, and generation of evidence. St. Louis, MI: Saunders Elsevier.

Gillespie, C. D., Wigington, C, & Hong, Y. H. (2013). Coronary heart disease and stroke deaths in United States. Supplements. 62(03), 157-160. doi:10.116.110.580092

Kim, T. K. (2015). T-test as a parametric statistic. *Journal of Korean Anesthesiology. 68*(6):540-546. doi:10.4097/kjae.2015.68.6.540

Libby, P. (2013). Mechanisms of acute coronary syndromes and their implications for therapy. *New England Journal of Medicine*, 368; 21. doi: 10.1056/NEJMrs1216063

Litmanovich, D. E., Ghersin, E., Burke, D. A., Popma, D. Shanhrzad, M., & Bankler, A. A. (2014). Imaging in transcatheter aortic valve replacement (TAVR): role of the radiologist. *Journal of Insights Imaging*, 5(1): 123-145 doi: 10.1007/s13244-013-0301-5

Mamas A. M., Anderson, S. G., Carr, M., Ratib, K., Buchan, I., Sirker, A., …, & Nolan, J. (2014). Baseline bleeding risk and arterial access site practice in relation to procedural outcomes after percutaneous coronary intervention. *Journal of the American College of Cardiology,* 64(15) http://dx.doi.org/10.1016/j.jacc.2014.05.07

Mean, G., End, C., & Kaul, P. (2017). Management of percutaneous coronary intervention complications. *Journal Cardiovascular Medicine*, 19(4), 25. doi: 10.1007/s11936-017-0526-6

Murphy, S. L., Kochanek, K. D., Xu, J. Q., & Arias, E. (2014). Mortality in the United States. *CDC.* Retrieved from https://pdfs.semanticscholar.org/7db0/3098b7355098e7e40b510782bf5274c88538.pdf

National Heart, Lung, and Blood Institute. (2017). What is coronary heart disease? Retrieved from https://www.nhlbi.nih.gov

Ozair, F. F., Jamshed, N., Sharma, A., & Aggarwal, P. (2015). Ethical issues in electronic health records: A general overview. *Journal of Perspectives in Clinical Research,* 6(2), 73-76. doi:10.4103/2229-3485.153997

Rao, S. V., Tremmel, J. A., Gilchrist, I. C., Shah, P.K. Gulati, R., Shroff, A. R., …. & Pancholy, S. B. (2013). Best practices for transradial angiography and intervention: A consensus statement from the society for cardiovascular angiography and intervention's transradial working group. *Journal of Catheterization and Cardiovascular Interventions.* 83(2): 228-236. doi:10.1002/ccd.25209

Roy, S. (2014). Atherosclerotic cardiovascular disease risk and evidence-based management. *North American Journal of Medical Sciences,* 6(5), 191-198. doi:10.4103/1947-2714.132916

Stevens, K. (2013). The impact of evidence-based practice in nursing and the next big ideas. *The Online Journal of Issues in Nursing,* 18(2): 4. doi:10.3912/OJIN.Vol18No02Man04

Stone, P. A., Thompson, S. N., Hanson, B., & Masinter, D. (2015). Management of femoral artery pseudoaneurysms in patients requiring coronary artery bypass grafting: Should the same treatment paradigm be used as those not undergoing CABG? *Journal of Vascular Surgery*, 62(3), 814. doi:http://dx.doi.org/10.1016/j.jvs.2015.06.120

Sutherland, K. (2013). Applying Lewin's change management theory to the implementation of bar-coded medication administration. Retrieved from http://cjni.net/journal/?p=2888

Valaker, I., Norekval, T. M., Raholm., M., Nordrehaug, J. E., Rotevatn., S., & Fridlund, B. (2017). Continuity of care after percutaneous coronary intervention: The patient's perspective across secondary and primary care settings. *European Journal of Cardiovascular Nursing*, 16(5), 444-452. doi:10.1177/14515117690298

Appendix A: Confidential Disclosure Agreement

CONFIDENTIAL DISCLOSURE AGREEMENT

This Agreement is entered into this_20__day of____July_____2017 by and between Nanticoke Health Services with Offices located at 801 Middle ford Rd Seaford Delaware 19973 (hereinafter "Discloser") and Kemi Sanni (hereinafter "Recipient").

Whereas Discloser possesses certain patient health information that is needed by the Recipient to complete her post-doctoral thesis activities (hereinafter "Confidential Information"); and

Whereas Recipient is willing to receive disclosure of the "Confidential Information" pursuant to the terms of this Agreement and

Now THEREFORE, in consideration for the mutual undertakings of the Discloser and the Recipient under this Agreement, the parties agree as follows;

Disclosure: Discloser agrees to disclose, the Recipient agrees to receive the "Confidential Information".

Confidentiality:

Recipient agrees to use its best efforts to prevent and protect the "Confidential Information" or any part thereof, from disclosure to any person other than Recipient's thesis committee that may have a need for disclosure in connection with Recipient's authorized use of the "Confidential Information".

Recipient agrees to take all steps reasonably necessary to protect the secrecy of the "Confidential Information", and to prevent the "Confidential Information" from falling into the public domain or into the possession of unauthorized persons.

Recipient agrees that all "Confidential Information" shall remain the property of Discloser, and the Recipient may use this information for the purpose listed above. The Recipient agrees that the "Confidential Information" will only be used as de-identifiied information and will not include medical record number, financial information number (FIN) or the patient's name for purposes of completing the thesis. Nothing contained herein shall be construed as granting or implying any transfer of rights to Recipient in the "Confidential Information" or other intellectual property protecting or relating to the "Confidential Information".

Recipient agrees to only obtain the "Confidential Information" that has been identified by the Department Leader for the area where the "Confidential Information" will be obtained. Information requested includes the following:

1. Total number of PCIs done per month over a six month period. Month one data, month two data, month three data etc.
2. Total number of PCIs by radial approach for each of the six months
    1. Total number of PCIs by radial approach that had complications and type of complications
3. Total number of PCIS by femoral approach for each of the six months
    1. Total number of PCIs by femoral approach that had complications and type of complications.

In WITNESS WHEROF, the parties have executed this agreement effective as of the date first written above.

Discloser: Nanticoke Health Services Lilia Kulmacz

Print Name: Lilia Kulmaczewski.

Title: Chief Compliance and Risk Officer

Date: 7-20-17

Recipient: K Sanni

Print Name: Kemi Sanni Date: 7/20/17

Appendix B: Letter from Dr. Gireesh

Al-vin Gireesh, MD. FACC.
801 Middleford Rd
Seaford, DE 19973
June 11, 2017

Dr. Janice Long
Chair Doctoral Committee
Walden University

Re: DNP Capstone Project for Kemi Sanni, DNP

Dear Dr., Long,

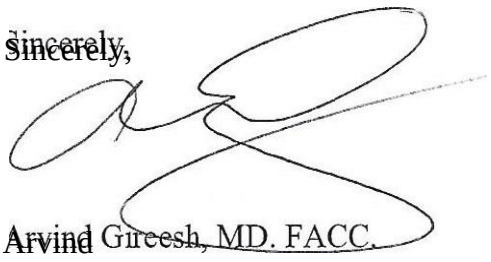
The letter is to affirm that I will be working with Ms. Kemi Sanni on the stated capstone project.

I am Interventional Cardiologist at Nanticoke Memorial Hospital. I perform a variety of coronary and peripheral artery interventions. Ms. Sanni will be working with me to evaluate these interventions to better understand our outcome data.

If you have any questions regarding the above, you can reach me at the above address.

Thank you.

Sincerely,



Arvind Gireesh, MD. FACC.

Appendix C: Clinical Guidelines for the Management of Post PCI Complications

Femoral Artery management

- Maintain a strict bedrest for 4-6 hours post-cath
- If sheath is applied to site, apply 20-30 minutes manual pressure to the site upon sheath removal
- Provide Foley catheter to prevent patient from getting up from the bed
- Monitor site for every hour for 2-4 hours
- If large pseudoaneurysms are suspected, proceed to the use of ultrasound-guided thrombin injection
- If superficial femoral arteries are used for the procedure, nurses should anticipate complication and be ready to intervene upon patient return to the unit

Radial Artery Management

- Do not remove air from the radial band for at least 120 minutes post procedure
- Complete neurovascular assessment every 15 minutes until air removal is completed
- If bleeding or hematoma is suspected, return radial band to decompress the site.
- Notify the interventionist immediately
- Assure patient that intervention will be implemented to alleviate anxiety