Catheter-to-Vessel Ratio and Catheter-Related Thrombosis in Peripherally Inserted Central Catheters: A Retrospective Review of Records

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Dedication

To my children, Hannah, Brendan & Colin, and to my parents, Lori and Steve. I could not have accomplished this without your love, support, encouragement, and patience. Mom and Dad, thank you for modeling and instilling in me my work ethic, perseverance and value of education, and for your constant encouragement that allowed me to achieve my DNP.

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Abstract

Catheter-related thrombosis (CRT) is a potential complication of peripherally inserted central catheters (PICCs). With PICC use becoming more common, it is important to minimize this complication. Selection of an appropriately sized vessel can reduce the risk of catheter-related thrombosis. Research suggests that using a catheter-to-vessel-ratio (CVR) of 45% or less can minimize this risk. This quality improvement project was implemented to evaluate the impact of utilizing an ultrasound device that can measure catheter-to vessel ratio with peripherally inserted central catheter insertion by the vascular access team.

Data was collected using a retrospective chart review looking at CRT rates before and after implementation of an ultrasound device that measures CVR to identify and use vessels with a CVR of 45% or less to insert PICCs. While there was no statistically significant difference, data suggests that using a CVR of 45% or less decreases the incidence of CRT. Results also reinforce previous research that cancer diagnosis as well as insertion of larger gauge PICCs were associated with deep vein thrombosis. Future studies that include larger sample sizes to validate this measurement are recommended.

Keywords: Catheter-to-Vessel-Ratio (CVR), Peripherally Inserted Central Catheter (PICC), Catheter-Related-Thrombosis (CRT), Deep Vein Thrombosis (DVT)

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Chapter 1

Introduction and Background

The use of peripherally inserted central catheters (PICCs) for vessel access has become increasingly prevalent because of the ease of insertion through the peripheral veins of the arm. PICCs can be used for a variety of reasons including administration of chemotherapy or antibiotics, are cost-effective, and associated with increased patient satisfaction (Sharp et al., 2014). While PICCs can prevent complications such as injury to the vessels of the neck and chest as well as pneumothorax, there are complications associated with this vascular access device (Chopra, 2020a).

Background

Catheter-related thrombosis (CRT) is a significant complication associated with the placement of PICCs. There are multiple risk factors for the development of CRT. These factors can be broadly categorized as: risks involving the line itself, risks related to the insertion process, and risks related to patient characteristics (Wall, Moore & Thachil, 2016). For the purpose of this project, the focus is on the line itself. The device related factor most frequently associated with CRT involves the size of the catheter (Chopra, 2020a). The diameter of the catheter in relation to the size of the lumen of the vein can directly impact CRT. If a catheter that is too large for the vein is placed, blood flow may be restricted potentially causing formation of a thrombus (Altawan, Golchian, Iijas, Patel & Bazzi, 2017). In addition, the friction contact between the lining of the vessel and the catheter in combination with reduced blood flow are potential causes of thrombosis. While thrombosis can result in destruction of the veins in the upper extremity and consequent loss of vascular access, the most notable complication is a pulmonary embolism (Leung, Heal, Perera & Pretorius 2015).

With the complication of CRT, it is important to note that there is an interruption in therapy, an increase in the cost of care and, as noted earlier, the potential of other consequences such as stenosis of the vein, phlebitis, and pulmonary embolism (Fallouh, McGuirk, Flanders, & Chopra, 2015). Other possible issues include bleeding related to anticoagulant therapy, bacteremia, sepsis, and prolonged hospitalization (Geerts, 2014). In hospitalized patients with PICCs the incidence of deep vein thrombosis (DVT) is between 5 and 15 percent (Chopra, 2020a). Estimates of the cost of the treatment of acute venous thromboembolism (VTE) and related complications range from $12,000 to $15,000 (Grosse, Nelson, Nyarko, Richardson & Raskob, 2016).

Though the literature is clear that the size of the catheter relative to the size of the vessel impacts the rate of CRT, there is limited research on the exact measurement necessary to decrease the incidence (Chopra et al., 2014; Sharp et al., 2014; Spencer & Mahoney, 2017). Recent studies suggest that a catheter to vessel ratio (CVR) of 45% or less decreases the risk of thrombus formation. CVR is defined as “indwelling space or area consumed or occupied by an intravascular device inserted and positioned within a venous or arterial blood vessel” (Sharp et. al, 2014; Spencer & Mahoney, 2017). In addition, the Infusion Nursing Society (INS) did not recommend a CVR in their 2007 and 2011 guidelines, however the 2016 INS Standards included new evidence stating that a CVR of less than or equal to 45% is recommended with PICC placement (Spencer & Mahoney, 2017; Wolters Kluwer, 2016). The utilization of a point-of-care ultrasound device allows health care providers to implement precision-based methods allowing for superior visualization and better assessment which in turn decreases complications (Spencer & Mahoney, 2017).

The health system that is the setting for this project recently purchased an ultrasound device that can accurately measure CVR. The purpose of this quality improvement (QI) project was to 1) fully implement the ultrasound device that can measure CVR, 2) compare pre- and post-implementation CRT incidence when using a CVR of 45% or less, and 3) determine if there is a decrease in the CRT rate when using the device.

Key Stakeholders

The main stakeholders of this project include patients with PICC access, vascular access team members and the vascular access team nurse manager. Secondary stakeholders include the Quality Improvement Team, attending physicians and hospital administration.

Clinical Question

In adult inpatients with PICCs placed by the vascular access team, will using a device that can accurately measure CVR of 45% or less compared to estimating the CVR without the device impact the CRT/DVT rate post PICC insertion?

Objectives

- Complete compliance using the new ultrasound machine that has the capability to measure an accurate CVR through advanced technology
- Decrease in the CRT/DVT incidence from 3 month pre-intervention data to post-intervention data

Methods

This QI project used a pre- and post-intervention design to look at the incidence of PICC related CRT before and after implementation of a device that can accurately measure catheter to vessel ratio. Pre-intervention data was collected retrospectively through chart review and included: PICC size, CVR, location of PICC, previous history of DVT or pulmonary embolism (PE), previous or current cancer diagnosis, anticoagulation medication, if any, and DVT/CRT resulting from the current PICC insertion. The same information with the addition of COVID diagnosis was collected post intervention for comparison.

Assumptions and Limitations

When choosing this project, it was assumed that the DVT incidence obtained from the health system was reflective of the overall incidence rate of PICC related DVTs. After data collection began, it was discovered that the DVT incidence data was the DVT incidence in symptomatic PICCs as opposed to all PICCs.

A major limitation of the project was the global pandemic that presented during the implementation of the new ultrasound device. This not only impacted patient characteristics, but the timeline of the project. Other limitations were sample size and time. With a larger sample size and longer time frame the data would be more comprehensive and equally reflective pre-and post-intervention. In addition, the project ended one month post data collection so a longer time period may have resulted in a difference in CRT incidence.

Chapter 2

Literature Review

Overview

This chapter includes a description of the theoretical framework, the Donabedian Model of Care, and a review of the literature on PICCs and CRT. It also describes concepts and definitions specific to the project. The literature review is divided into the following sections: catheter and vessel size, catheter to vessel ratio, ultrasound, associated conditions, asymptomatic VTE, and gaps in the literature/strengths and summary.

Concepts/terms Definitions

For the purpose of this project, catheter to vessel ratio (CVR) is defined as "the indwelling space of area consumed or occupied by an intravascular device inserted and positioned within a venous or arterial blood vessel" (Spencer & Mahoney, 2017, p. 428). A PICC is a peripherally inserted central catheter. Catheter-related thrombosis (CRT) refers to the development of a thrombus (blood clot) resulting from the placement of a PICC (Leung, Heal, Perera, & Pretorius, 2015). Venous thromboembolism (VTE) refers to deep or superficial thrombosis.

Conceptual Framework

The Donabedian Model of Care is a model for evaluating quality of care. The model is comprised of three components: structure, process, and outcome and can be used for outcomes assessment (Ayanian & Markel, 2016; NHS Improvement, 2018). Structure includes the organizational and physical elements where healthcare occurs. These are considered input measures (NHS Improvement, 2018). Process centers on the delivery of care and reflects on the way the systems and process work together to produce the desired outcome. The process needs to be evaluated to formulate an intervention to impact the outcome (NHS Improvement, 2018). Outcome involves the impact of healthcare on the patient and populations and if the goal was achieved. Outcome describes if the clinical care has been implemented effectively. This is where the connection between change and outcome is established and is the true validator of the effectiveness and quality of care (Ayanian & Markel, 2016; NHS Improvement, 2018).

This QI project measured outcomes after an evidence-based change in practice. The standard of practice for PICC insertion at the health care system was having the vascular access team estimate the size of the vein via ultrasound and insert the PICC based on their estimate of vein size. An ultrasound device was purchased that has the ability to measure CVR. For the project, the new device was used to measure the CVR for all PICC insertions. Pre-intervention VTE incidence was compared with post-intervention VTE incidence to evaluate the change in the delivery of care. The three components of the Donabedian model provided a framework for the project which took an existing practice, changed the process, and measured outcomes (see Figure 1).

Review of Literature

A literature review was conducted to gather information regarding PICC insertion, CVR, and CRT. The databases searched for literature were CINAHL, PubMed, and Medline Complete. The keywords and phrases included in the search were: *catheter to vessel ratio, catheter-related thrombosis, and PICC.* Parameters included publication between 2014 and 2020, peer-reviewed, and English language. Initially including the term *catheter to vessel ratio* significantly limited results, therefore the search term was removed. A total of 129 articles resulted from searches of the three databases; duplicate studies were removed. Studies exclusive to cancer patients, intravenous access other than PICCs, PICC removal, thrombosis treatment, and studies specific to the pediatric population were excluded. In addition, two articles were accessed by reviewing references of articles produced by the search, and a chapter of a book specific to vessel health and preservation published in 2019 were included. One article published in 2011 was also included as it was referenced in many of the reviewed articles. Additionally, two articles from the UpToDate website were utilized as this site provides current evidence-based practice. The search was implemented in August of 2020 and reevaluated throughout the project for any new evidence.

A total of 14 articles and one book were reviewed. Eight of the articles were literature reviews, three were cohort studies, one nested case control, one simulated model study, and one was the Infusion Nurses Society Infusion Standards of Practice. Study settings ranged from a 145 bed VA hospital to a multicenter health system encompassing 48 hospitals; only studies with adults were included. The majority of the studies used medical record reviews, however, two included follow up with an ultrasound or a phone call. While the primary focus of the search was on PICC insertion and catheter related thrombosis, studies were included that discussed patients with conditions that put them at higher risk as this will impact the results of the project.

Catheter and Vessel Size

An increased risk of CRT associated with the size of the catheter in relation to the size of the vessel was consistent throughout all of the articles that were reviewed. Several articles mentioned how thrombus formation may be a result of increased friction from the presence of the lumen in the vein (Fallouh et al., 2015; Geerts, 2014; Leung et al., 2015; Sharp et al., 2014; Spencer & Mahoney, 2017). Greene, Flanders, Woller, Bernstein, and Chopra (2015) described the physiologic impact of PICCs in terms of how they occupy a sizable amount of the diameter of the vessel which can predispose venous stasis. In a retrospective cohort study implemented across 48 hospitals, they found the risk-adjusted hazard of upper extremity thrombosis was ten times greater in patients with PICCs compared to those without a PICC. In a simulated model of PICCs looking at the effect of CVR on blood flow rates, Nifong and McDevitt (2011) determined that fluid flow decreased significantly with the insertion of a PICC and that the size of the catheter related to the vessel size has a direct impact on the reduction of flow.

Blood stasis, vascular injury, and hypercoagulability make up Virchow's triad, a basic part of physiology that may factor into complications related to PICC insertion (Altawan et al., 2017; Greene et al., 2015; Nifong & McDevitt, 2011; Sharp et al., 2014; Spencer & Mahoney, 2017; Wall et al., 2016). A key element of thrombosis is stasis and since blood flow has its greatest velocity at the center, a PICC positioned in the center of the vein has a considerable effect on blood flow (Sharp et al., 2014). Wall et al. (2016) described how damage to the vessel can be caused by catheter insertion, stasis by the presence of the catheter, and a hypercoagulable state from inflammation potentially from the insertion of the line.

The diameter of the catheter in relation to the size of the vein impacts the ability of blood to flow freely or stagnate (Altawan et al., 2017; Chopra, 2020; Chopra et al., 2015; Fallouh et al., 2015; Geerts, 2014; Nifong & McDevitt, 2011; Sharp et al., 2014; Wall et al., 2016). A VTE is more likely to form in a smaller vein with a larger catheter as opposed to a larger vein with a smaller catheter (Altawan et al., 2017; Chopra, 2020). A retrospective cohort study implemented at a 145 bed Veterans Medical Center utilized records from 966 PICC placements noted that patients with 5 French and 6 French catheters not only had a higher risk but developed VTE earlier than those with a 4 French catheter (Chopra et al., 2014). Researchers in a nested case-control study (Chopra et al., 2015) echoed the retrospective cohort study and found that individuals who had PICCs with a larger gauge had a greater risk of developing a CRT compared to those who had smaller devices (6-French as opposed to a 4-French). The study included a review of the electronic medical records of 909 patients and a vascular access database and was implemented over a year at an academic medical center.

Nifong and McDevitt (2011) utilized fluids and glass cylinders to measure flow rates with different catheter sizes. They measured the flow rate for each cylinder and catheter grouping five times and found a statistically significant change with each increase in the size of the catheter which is in line with evidence that the risk of VTE increases with larger catheters. An article by Wall et al. (2016) supports this finding citing studies that suggest increasing lumen size increases the risk of CRT and recommends that if PICCs are being used, CVR needs to be considered to decrease the risk of CRT. An article written by Geerts (2014) reinforces this citing evidence that the use of multi-lumen PICC devices is associated with a significantly increased rate of CRT than a catheter with a single lumen (3.0% vs 1.9%).

Catheter to Vessel Ratio

The book *Vessel Health Preservation: The Right Approach for Vascular Access* (Moureau, 2019) introduces the Vessel Health and Preservation Model (VHP). The model incorporates evidence-based practice, guidelines, and recommendations to ensure increased safety, decreased risk, and a decrease in complications when using a vascular access device (VAD). The model stresses the importance of selecting the best vein and device for vascular access and recommends a VAD size that does not exceed 33% of the diameter of the vessel.

A prospective cohort study implemented by Sharp et al. (2014) suggested that a CVR of 45% or less should be utilized when placing PICCs. PICCs that did not follow this rule were associated with 13 times increase in the incidence of VTE. The 45% ratio cut-off point demonstrated high specificity and sensitivity. In addition, there was no difference in risk when the analysis included lower ratios suggesting that it may be unnecessary to use a CVR of 33% or less.

Spencer and Mahoney (2017) developed a standardized process of ultrasound-guided assessment of vessel selection. After a comprehensive search of the literature, the authors were unable to find literature to support a 33% CVR which was commonly used as the “rule of thumb” for VAD insertion. They note that despite the focus on the risk of VTE and large diameter PICCs there is limited evidence on the CVR. While the Infusion Nursing Society (INS) did not recommend a CVR in their 2007 and 2011 guidelines, the 2016 INS Standards included new evidence stating that a CVR of less than or equal to 45% is recommended with PICC placement (Spencer & Mahoney, 2017; Wolters Kluwer, 2016). In an UpToDate review of literature, Chopra (2020) also recommends that a PICC should only be inserted if the CVR is equal to or less than 45%.

Ultrasound

A core component of the VHP model discussed by Moureau (2019) is assessment of the vessel via ultrasound. Ultrasound for vessel site selection is utilized to identify and map structures for optimal device insertion. This includes scanning peripheral vessels without the use of a tourniquet to assess the vessel in its normal condition. It can assess the depth and patency of the vessel as well as identify anatomic variations and the presence of thrombosis. This recommendation is reinforced in the *Infusion Therapy Standards of Practice* (Wolters Kluwer, 2016) where it is recommended to use ultrasound to assist in vessel identification and selection to decrease adverse events as well as success with the first insertion attempt.

Chopra (2020a) cites a lack of ultrasound use for PICC placement as a risk factor for VTE. Similarly, Sharp et al. (2014) notes the importance of vein measurement using ultrasound to ensure that an appropriately sized vessel is identified for PICC placement to decrease the risk of VTE. As mentioned earlier, Spencer & Mahoney (2017) developed a risk reduction tool to reduce CRT; the foundation of the tool is the measurement of CVR via ultrasound.

Associated Conditions

The presence of preexisting conditions can impact the incidence of CRT (Chopra, 2020a; Chopra et al.,2014; Chopra et al., 2015; Fallouh et al., 2015; Greene et al., 2015; Leung et al., 2015). A prospective cohort study implemented by Sharp et al. (2104) noted that all of the individuals who developed a VTE had a hematological malignancy, including one whose CVR was 30% as opposed to 45%. Chopra et al. (2014) had similar findings noting that a cancer diagnosis within six months before PICC insertion as well as a larger catheter gauge were the strongest predictors of CRT. The article also mentions how previous studies have noted that thrombosis in cancer patients can be triggered by or associated with vascular access devices.

Several patient-related factors associated with VTE were mentioned in a narrative review of 83 articles (Fallouh et al., 2015). These conditions include critically ill patients, patients diagnosed with cancer as well as patients with end-stage renal disease, diabetes, obesity, and with chronic obstructive pulmonary disease. In addition, patients who have surgery with an indwelling PICC are at an increased risk. Many of the studies in the review were observational. Chopra et al. (2015) also noted that patients who underwent surgery with a PICC, as well as patients with a history of VTE, were at greater risk.

Leung et al. (2015) implemented a systematic review of patient related risk factors for CRT and found conflicting information. Of the eight studies looking at malignancy as a comorbidity, six found no effect. On a multivariate analysis, two retrospective cohort studies found a positive association between malignancy and CRT. Only one of seven studies looking at surgery as a risk factor found a significant association. Diabetes as a risk factor was explored in eight studies, three of which found significant association, five did not. In a prospective cohort study of 76,242 patients, Greene et al. (2015) noted predictors such as prior hospitalization, a cancer diagnosis, and prior VTE were associated with an increased risk for CRT. In a review of literature, Chopra (2020a) discusses a systematic review of 64 studies. The review indicated that critically ill individuals with PICCs had the highest incidence of CRT with a prevalence of 13%, followed by a 6% prevalence in individuals with cancer.

Asymptomatic VTE

Many studies indicated that a high percentage of VTEs are asymptomatic (Ayanian & Markel, 2016; Chopra et al., 2014; Fallouh et al., 2015; Leung et al., 2015). While symptomatic VTE typically presents with swelling, pain, erythema, and warmth, often CRTs are asymptomatic (Fallouh et al., 2015). A systematic review implemented by (Leung et al., 2015) indicated that up to 66% of CRT can be asymptomatic. Chopra et al. (2014) referenced similar findings of a randomized controlled clinical trial that used ultrasound to screen for CRT. Up to 75% of the individuals with PICCs were identified as having a VTE; only four percent of these individuals had clinical symptoms. This was reiterated by Altawan et al. (2017) who discuss the incidence of symptomatic upper extremity VTE ranging from three to 20 percent and asymptomatic VTE reported up to 61.9%.

Gaps/Strengths

While the literature is clear that the size of the catheter in relation to the size of the vessel impacts the incidence of CRT, there is limited research on the exact measurement necessary to significantly decrease the incidence (Chopra et al., 2014; Sharp et al., 2014; Spencer & Mahoney, 2017). Although evidence is limited regarding a specific measurement of CVR, the

Infusion Therapy Standards of Practice most recent recommendations include a CVR of 45% or less for PICC insertion as well as the use of ultrasound to determine optimal placement of the line (Wolters Kluwer, 2016). This is reflected in a PICC insertion tool created by Spencer & Mahoney (2017), a prospective cohort study implemented by Sharp et al. (2014), and the literature review executed by Chopra (2020). Validation of this measurement requires further study.

The literature also indicates that a cancer diagnosis can increase the risk of CRT (Chopra et al., 2014; Fallouh et al., 2015; Leung et al., 2015; Sharp et al., 2014). For the purpose of this literature search studies exclusive to cancer, PICCs, and VTE were eliminated. Despite this elimination, the studies that were included in the search still strongly suggest this association. It is essential to understand this when moving forward with future research and to identify and control for patients with a cancer diagnosis. Several other comorbidities related to an increased VTE risk were suggested in the literature with conflicting results. This is another implication for clinical practice in order to identify patients who are at a higher risk for VTE and monitor outcomes closely. Future research is needed to clarify previous studies and identify VTE risk associated with comorbidities.

An important factor to keep in mind is the incidence of asymptomatic CRT noted in the review of literature (Ayanian & Markel, 2016; Chopra et al., 2014; Fallouh et al., 2015; Leung et al., 2015). Combining this with the potential increased incidence in some populations, it is essential to identify and utilize the CVR consistently when inserting PICCs. It is also important to note that of the 14 articles reviewed, eight were literature reviews, and only four were studies, one a simulated study, again, reinforcing the need for further research.

Chapter 3

Methods

This QI project used a pre and post intervention design to examine the incidence of PICC related thrombosis before and after implementation of a device that can accurately measure catheter to vessel ratio.

Setting

This project was conducted at a non-profit health care system that serves parts of the greater Philadelphia area and its western suburbs. The core values of the health care system include safety, innovation and teamwork/systemness. The system is composed of four acute care hospitals with approximately 1200 licensed beds that provide a wide variety of inpatient and outpatient services. Each hospital in the system is staffed with a vascular access team. There are approximately 50 vascular access Registered Nurses employed by the health care system.

Sample

The sample for this project was adult inpatients who had a PICC placed by the vascular access team in one of the four hospitals in the health care system. Patients under 18 were excluded from the study. Patients who had a diagnosis of COVID as well as patients who had their PICC placed in Interventional Radiology were also excluded.

Ethical Considerations

A project proposal was submitted to the Office of Research Protections at the health care system. After review, the project was deemed a QI project and therefore does not require approval from the health care system's Institutional Review Board (Appendix A). The project was a record review only and there will be no access to patients. The project proposal was submitted to and approved by the West Chester University Institutional Review Board (Appendix B).

Project Design/ Data Collection Tools

This QI project employed the use of an interventional pre and post design. The pre-and - post design measures the occurrence of an outcome before and after the intervention is applied. Outcomes measured during this type of project can be binary outcomes such as incidence or prevalence (Thiese, 2014).

Pre-intervention data was collected retrospectively through a chart review. Information was recorded on a spreadsheet and included PICC size, CVR, location of PICC, previous history of DVT or PE, previous or current cancer diagnosis, anticoagulation medication, if any, and DVT/thrombosis resulting from the current PICC insertion (Appendix C). The intervention was implementation of an ultrasound device that can accurately measure a catheter to vessel ratio of 45% or less. The same information was collected post intervention for comparison. Based on the time frame of the project and data collected during the chart review, the patients COVID testing results were included in data collection, however, these patients were excluded from the project. The study period compares an equal length of time before and after the intervention.

Data Analysis

Data collected between August 1, 2019 and October 31, 2019 was considered pre-intervention data and data collected between November 1, 2020 and January 31, 2021 was considered post-intervention data. Data was analyzed using Stata/MP 15.1 (StataCorp LP., Texas, USA). Statistical significance was assessed at the 5% level, where applicable, and all tests were two-sided. A biostatistician assisted with data analysis.

Patient characteristics (age, sex, history of DVT/PE, anticoagulant use, cancer diagnosis, COVID diagnosis), PICC characteristics (previous PICC, PICC gauge, PICC location, PICC side), and outcomes (DVT with PICC, thrombosis with PICC, DVT or thrombosis with PICC) were compared between the pre-intervention and post-intervention periods separately for each hospital, and then systemwide. Patient and PICC characteristics were compared between the pre- and post-intervention periods using two-sample *t* tests and Chi-squared tests of Independence. Normality was assessed for continuous variables using histograms.

The *p*-values were not calculated comparing DVT and thrombosis rates between pre-and post-intervention periods due to insufficient statistical power. Instead, rates are displayed descriptively, and 95% confidence intervals (95% CI) were computed for each rate using the exact binomial method.

Additional descriptive analyses were performed to compare patient and PICC characteristics between patients with a DVT, thrombosis, or DVT/thrombosis, respectively.

Resources

The ultrasound device had previously been purchased for all of the hospitals in the system. The vascular access team was formally trained by a company representative and there was a manual for reference if there were any questions or issues. A new data collection tool was created to document when using this device. Initially it was a paper form that was scanned into the electronic health record, but it was changed to a field in the electronic health record used by the health system. Information housed in this tool includes: the CVR, vessel where the PICC was placed and the size of the PICC catheter. Other information collected includes the reason for the PICC, history of DVT or PE, anticoagulant medication (if any), pertinent laboratory values and previous PICC history. The ultrasound device was preset for a catheter to vessel ratio of 45% or less. There was no extra cost for this project to be implemented.

Key Stakeholders

The main stakeholders of this project include patients with PICC access, vascular access team members and the vascular access team nurse manager. Secondary stakeholders include the QI team, attending physicians and hospital administration since it is imperative to provide evidence based, safe, and effective care to patients.

Timeline

July 2020 – November 2020

- Met with preceptor to discuss details of project
- Met with biostatistician to discuss details of project
- Met with vascular access team nurse to discuss data collection tool and ultrasound device
- Submitted IRB application to West Chester University
- Submitted project proposal to the health care system's Office of Research Protections/IRB

December 2020 – March 2021

- Gathered retrospective data
- Met with preceptor to discuss project progress and potential barriers
- Gathered prospective data
- Met with biostatistician to review and analyze data

April 2021

- Met with preceptor/vascular access team nurse manager to discuss findings
- Presented findings/results

Rigor

Inclusion and exclusion criteria were strictly followed when implementing the chart review and post-intervention data collection. All data was stored on a password protected computer. Any paper copies were secured in a locked filing cabinet in a locked office.

Plans to Disseminate

Results will be distributed at both the hospital and the health system levels. The data will be presented to the vascular access team, hospital administration and QI personnel. A manuscript may be written and submitted for publication in a peer-reviewed journal.

Chapter 4

Results

This project was a retrospective record review to look at the impact of using a catheter-to-vein ratio of 45% or less when placing a PICC and its relationship to CRT incidence. A biostatistician who was not associated with the project but associated with the health care system in which the project was conducted assisted with data analysis.

Patient/PICC Characteristics

There were no significant differences in patient age (p=0.397), sex (p=0.371), PICC location (p=0.868), PICC side (p=0.145), history of DVT or PE (p=0.132), and previous PICC (p=0.896) between the pre- and post-intervention groups (Table 1). The average (SD) patient age in the pre- and post-intervention groups was 67.5 (14.9) and 66.6 (15.2), respectively. The majority of patients in both groups were male (60.7% vs. 57.8%) (Table 1).

PICC gauge differed significantly between the two groups (p=0.001). The majority of patients in both groups had a gauge size of 5 (68.3% vs. 79.1%), however, the pre-intervention group was significantly more likely to have a gauge size of 4 (31.7% vs. 20.7%). PICC location did not differ between the two groups, as 80% of both groups used the basilic vein. In addition, most of the patients in both groups had the PICC on their right side (83.1% vs. 79.3%) (Table 2).

Anticoagulant use differed significantly between the two groups (p=0.011). 25.2% of those in the pre-intervention group and 29.6% of those in the post-intervention group did not use any anticoagulants. About 18% of patients in both groups used aspirin alone, and 35.3% in the pre-intervention group and 32.4% in the post-intervention group used another type of anticoagulant alone. About 20% of patients in both groups used a combination of anticoagulants

(21.7% vs. 19.3%) (Table 2). The pre-intervention group was significantly more likely to have a cancer diagnosis (25.9% vs. 17.3%; *p*=0.002). There were no significant differences in the percent of patients with a history of a DVT or PE (11.1% vs. 14.5%) or having a previous PICC (83.4% vs. 83.7%) between the two groups (Table 1).

The rate of DVT with PICC (1.3% [95% CI: 0.4% - 2.9%] vs. 0.4% [95% CI: 0.04% - 1.4%]) and thrombosis with PICC (1.0% [95% CI: 0.2% - 2.6%] vs. 0.6% [95% CI: 0.1% - 1.75%]) decreased between the pre- and post-intervention periods. Combining outcomes, 2.3% (95% CI: 1.0% - 4.3%) of the pre-intervention group and 1.0% (95% CI: 0.3% - 2.3%) of the post-intervention group had a DVT or thrombosis with PICC.

In the post-intervention period, 27.8% of patients had COVID. The average (SD) CVR was 31.0 (10.4). 14.3% of patients had a CVR < 20, 48.4% had a CVR between 20-35, 35.1% had a CVR between 36-45, and 2.2% (n=11) patients had a CVR > 45.

DVT

There were no major differences in the average patient age between those without and with a DVT. The average age in both groups was about 66 years old. Males and females had similar rates of DVT (0.9% vs. 0.6%).

The rate of DVT increased as PICC gauge size increased. No patients with a PICC gauge of 3 experienced a DVT, whereas 0.5% of those with a size 4 had a DVT and 0.9% of those with a size 5 had a DVT. No patients who had a PICC in the cephalic vein experienced a DVT. Conversely, 1.6% of patients who had a PICC in the brachial vein and 0.7% of patients who had a PICC in their basilic vein experienced a DVT. Patients who had a PICC on the left side were more likely to experience a DVT (1.4% vs. 0.7%). Combining PICC side and location, most patients had a right basilic PICC, and the DVT rate in this group was 0.6%.

One of the six DVTs occurred in a patient who was not on any anticoagulant, and the remaining five occurred in patients who were on a single anticoagulant other than aspirin. The rate of DVTs was 2% among patients who took a single anticoagulant other than aspirin. None of the aspirin alone patients experienced a DVT.

Patients with a cancer diagnosis were slightly more likely to experience a DVT (1.2% vs. 0.7%). Patients with a history of DVT or PE were more likely to experience another DVT (3.2% vs 0.5%). Patients with a previous PICC were also more likely to experience a DVT (1.0% vs 0%). In the post-intervention group, there was only one DVT, and it occurred in a patient with a CVR between 36-45.

Thrombosis

There were no major differences in the average patient age between those without and with a thrombosis. The average (SD) patient age in patients without a thrombosis was 67 (15.6) and 65.6 (19.8) in patients with a thrombosis. Males and females had similar rates of thromboses (1.1% vs 0.6%).

There was only one patient with a PICC gauge of 3, and they did not experience a thrombosis. The rate of thrombosis was 0.9% in patients who had a gauge of 4 and 5. All seven thromboses occurred in patients who had a PICC placed in the basilic vein. Additionally, all thromboses except for one occurred in patients who had a PICC on the right side. All thromboses except for one occurred in patients who were not taking anticoagulants. The other thrombosis occurred in a patient who had a combination of anticoagulants.

The rate of thrombosis was similar between those with vs without cancer (1.2% vs. 0.9%). All seven thromboses occurred in patients who did not have a history of DVT or PE. Additionally, all thromboses except for one occurred in patients who had a previous PICC.

In the post-intervention group, there were three cases of thrombosis. Two of the three occurred in patients with a CVR between 20-35, and the last occurred in a patient with a CVR between 36-45. No thromboses occurred in patients with a CVR < 20 or > 45.

DVT or Thrombosis

There were no major differences in the average patient age between those without verses those with a thrombosis or DVT. The average (SD) age for patients without these events was 67 (15.6) and the average was 65.8 (17.5) for patients with a thrombosis or DVT. Males were slightly more likely to have a DVT or thrombosis (2.0% vs 1.3%).

The rate of DVT or thrombosis was slightly higher among patients with a PICC gauge of 5 (1.9%) compared to those with a gauge of 4 (1.4%). No events happened in patients who had the PICC in the cephalic vein. The rate of DVT/thrombosis was similar in patients who had the PICC in the basilic (1.8%) and brachial (1.6%) veins. There were minor differences in the rate of DVT/thrombosis between those who received their PICC on their right (1.6%) vs left (2.1%) side.

The rate of DVT/thrombosis was highest among those without any anticoagulant use (3.4%). No patients who were on aspirin alone experienced a DVT or thrombosis. 2% of those on a single anticoagulant other than aspirin experienced a DVT or thrombosis, and 0.6% of those on more than one anticoagulant experienced a DVT or thrombosis.

Patients with cancer were slightly more likely to experience a DVT or thrombosis (2.4% vs 1.5%). Patients with a history of DVT or PE were two times more likely to experience a DVT or thrombosis (3.2% vs 1.5%) than those without a history. Those with a previous PICC were also more likely to experience a DVT or thrombosis (1.9% vs 0.8%). In the post-intervention group, 2/4 DVT or thromboses occurred in patients with a CVR between 20-35, and the other 2/4 occurred in patients with a CVR between 36-45. No DVT or thromboses occurred in patients with a CVR < 20 or > 45.

After excluding the COVID patients, there were six cases of DVT, seven cases of thrombosis, and 13 cases of DVT or thrombosis in the full patient cohort (combining pre-intervention and post-intervention).

Systemwide, after excluding the COVID patients, the pre- vs post-intervention rates were:

- DVT: 1.3% vs 0.3%
- Thrombosis: 1.0% vs 0.8%
- DVT or Thrombosis: 2.3% vs 1.1%

Chapter 5

Discussion

While there are many advantages to using PICCs, they can be associated with upper extremity DVTs which can lead to a delay in treatment, a potential increase in length of stay, and medical complications (Chopra et al., 2014). Though there are many factors that can contribute to this, one controllable factor is the size of the catheter in relation to the size of the vessel. Studies suggest that using a CVR 45% or less can decrease the incidence of PICC related thrombosis (Sharp et al., 2014). By implementing a device that can accurately measure CVR, the incidence of DVTs in patients with PICCs may be decreased.

The purpose of this QI project was to evaluate the effectiveness of an ultrasound device that can measure CVR and determine if accurate measurement of a CVR of 45% or less decreased the DVT rate in patients with PICCs placed by the vascular access team. While the sample size was too small to note a statistical difference, there was a decrease in DVTs and thrombosis pre-and post-intervention. In addition, several findings were consistent with previous research.

Sample Characteristics

System-wide pre-and post-intervention groups were similar in age and gender. While the majority of patients in both groups had a PICC gauge size of 5, the pre-intervention group was more likely to have a gauge size of 4 than the post-intervention group. Side and vessel location was similar in both groups as well as previous PICC, DVT/PE. Use of anticoagulants as well as cancer diagnosis differed significantly between the pre-and post-intervention groups.

Approximately 28% of the post-intervention group had a COVID diagnosis; results were calculated both including and excluding these patients for comparison.

Key Findings

Since the DVT incidence was low to begin with, the sample was not large enough to demonstrate statistical significance, however, the incidence did decrease post-intervention. In addition to DVTs, the ultrasound results from symptomatic patients included thrombosis and this information was included in the results. Similar to the DVT data, the incidence of thrombosis also decreased post-intervention (Figure 2).

Patients with a history of DVT or PE were twice as likely to experience a DVT or PE than those with no history (Figure 3). In addition, patients with a previous PICC were also more likely to experience a DVT or thrombosis (Figure 4).

In patients with DVTs, all occurred in patients taking an anticoagulant other than aspirin alone. In patients with thrombosis, all except for one occurred in patients on no anticoagulants; the one occurred in a patient on a combination of anticoagulants. No patients on aspirin alone experienced a DVT or PE.

While no PICCS should have been placed in a vessel with a CVR greater than 45, nine were. No DVTs or thromboses occurred in patients with a CVR < 20 or > 45. It is interesting to note that no DVT or thromboses occurred in PICCs placed in the cephalic vein; there was minimal difference between PICCs placed in the left vs right side.

Theoretical Framework

This project correlates with the Donabedian Model of Care looking at the impact of a practice change on patient outcomes. The model is composed of three components: structure, process, and outcome and can be used for outcomes assessment (Ayanian & Markel, 2016; NHS Improvement, 2018). This QI project measured outcomes after an evidence-based change in practice. The standard of practice for PICC insertion in the health care system was having the vascular access team estimate the size of the vein via ultrasound and insert the PICC based on their estimate of vein size. The project evaluated DVT/thrombosis rates after implementation of a new device that was used to measure the CVR for all PICC insertions. Pre-intervention DVT/thrombosis incidence was compared with post-intervention DVT/thrombosis incidence to evaluate the change in the delivery of care. The Donabedian model guided the project which took an existing practice, changed the process, and measured outcomes.

Consistent Findings

Overall, the results were consistent with previous research. As noted by Chopra et al. (2014) cancer diagnosis as well as insertion of larger gauge PICCs were strong predictors of DVT. Sharp et al. (2014) and Fallouh et al. (2015) also discussed an increased incidence of CRT in individuals with a diagnosis of cancer. Both of these factors were noted in the findings of the project.

The most recent recommendations of the *Infusion Therapy Standards of Practice* include using a CVR of 45% or less for PICC insertion as well as the use of ultrasound to determine optimal placement of the line (Wolters Kluwer, 2016). This is reflected in a PICC insertion tool created by Spencer & Mahoney (2017), a prospective cohort study implemented by Sharp et al.

(2014), and the literature review executed by Chopra (2020). Using these recommendations, the implemented project also noted a decrease in CRT.

Implications for Practice, Education, Policy & Research

The findings of this project suggested that utilization of an ultrasound device that can accurately measure CVR decreased the incidence of DVT and thrombosis in patients with PICCs placed by the vascular access team using CVR of 45% or less. All vascular access staff in the health system should be trained in use of the device as well as accurate documentation. A competency has been created and should be used to train and reinforce training for PICC placement.

A policy should be written regarding use of the device including that only vessels with a CVR of 45% or less should be utilized for PICC placement by vascular access team staff. In addition, documentation should be consistent across the hospitals in the health system.

Future research using a longer time frame with a larger sample size is recommended based on the results of this project. In addition, it would be interesting to look at anticoagulant use in relation to PICC-related DVT/thrombosis. While many of the patients were on anticoagulants for other medical reasons, the relationship could be further investigated.

Limitations

A major limitation of the project was the presence of the COVID pandemic. This not only impacted the timeline of the project but also the sample characteristics. Having a longer period perhaps two years to compare pre-and post-intervention groups would have allowed for a larger sample size in addition to looking at the same time of year pre-and post-intervention. In addition, the project concluded one month after the post-intervention PICC data was collected.

Since PICCs can be used for months after insertion, there is a chance DVTs/thromboses were missed.

Differences in documentation across the health system was another limitation. Each hospital in the system had a slightly different way of documenting baseline information of PICC insertion. While ultimately the information was obtained from the patient record, it was often difficult to find. Also, the electronic medical record was changed in 2018. Data prior to 2018 was not uploaded into the system so some medical history may have been incomplete.

Generalizability

Since the project was implemented across a health care system composed of 4 hospitals with a defined population it can be generalizable to other health care facilities.

Reliability/Validity

The same investigator used the same collection form and method when reviewing the patient charts. There were instances that charts did not have all of the information in the same location, but all of the same areas of each chart were reviewed to get the most consistent and comprehensive information. This was a small study with a limited amount of time which may have impacted the reliability and validity of the results.

Conclusion

The outcome of this project reinforces previous research that using a CVR of 45% or less can decrease the incidence of CRT. While there are many factors that impact PICC-related CRT, the choice of the size of the catheter in relation to the size of the vessel is controllable. Utilizing a device that can accurately measure the CVR allows vascular access nurses to choose an appropriate vessel helping to eliminate this factor.

This project was implemented in a health system that is composed of four hospitals. While there were minor differences in documentation across the system, the overall results were similar. Though the results of the project are promising, further research is necessary to validate the findings as well as to look at other controllable factors such as anticoagulant use and vessel site selection that might potentially impact the risk of CRT.

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Table 1

Distribution of Patient Demographics by Intervention Period (Column Percentages Shown)

	System-wide		
	Pre-Intervention (n = 397)	Post-Intervention (n = 497)	p-value
Patient Age, Mean (SD)	67.5 (14.9)	66.6 (15.2)	0.397
Patient Sex, n(%)			0.371
Female	156 (39.3%)	210 (42.3%)	
Male	241 (60.7%)	287 (57.8%)	
Cancer Diagnosis, n(%)			**0.002**
No	294 (74.1%)	411 (82.7%)	
Yes	103 (25.9%)	86 (17.3%)	
History of DVT or PE, n(%)			0.132
No	353 (88.9%)	425 (85.5%)	
Yes	44 (11.1%)	72 (14.5%)	
COVID, n(%)			N/A
No	---	359 (72.2%)	
Yes	---	138 (27.8%)	
Previous PICC, n(%)			0.896
No	66 (16.6%)	81 (16.3%)	
Yes	331 (83.4%)	416 (83.7%)	

SD = Standard Deviation; N/A = Not Applicable

Table 2

Distribution of PICC Characteristics by Intervention Period (Column Percentages Shown)

	System-wide		
	Pre-Intervention (n = 397)	Post-Intervention (n = 497)	p-value
PICC Gauge, n(%)			**0.001**
3	0 (0.0%)	1 (0.2%)	
4	126 (31.7%)	103 (20.7%)	
5	271 (68.3%)	393 (79.1%)	
PICC Location, n(%)			0.868
Basilic	320 (80.6%)	400 (80.5%)	
Brachial	68 (17.1%)	83 (16.7%)	
Cephalic	9 (2.3%)	14 (2.8%)	
PICC Side, n(%)			0.145
Left	67 (16.9%)	103 (20.7%)	
Right	330 (83.1%)	394 (79.3%)	
PICC Side and Location, n(%)			0.324
Left Basilic	44 (11.1%)	78 (15.7%)	
Left Brachial	19 (4.8%)	22 (4.4%)	
Left Cephalic	4 (1.0%)	3 (0.6%)	
Right Basilic	276 (69.5%)	322 (64.8%)	
Right Brachial	49 (12.3%)	61 (12.3%)	
Right Cephalic	5 (1.3%)	11 (2.2%)	
CVR, Mean (SD)	---	31.0 (10.4)	N/A
< 20	---	71 (14.3%)	
20-35	---	240 (48.4%)	
36-45	---	174 (35.1%)	
> 45	---	11 (2.2%)	

Anticoagulant, n(%)			**0.006**
None	100 (25.2%)	147 (29.6%)	
Aspirin Alone	71 (17.9%)	93 (18.7%)	
Heparin Alone	61 (15.4%)	44 (8.9%)	
Lovenox Alone	39 (9.8%)	66 (13.3%)	
Eliquis Alone	21 (5.3%)	39 (7.9%)	
All Other Single Anticoagulants	19 (4.8%)	12 (2.4%)	
Combination	86 (21.7%)	96 (19.3%)	
Anticoagulant, n(%)			0.430
None	100 (25.2%)	147 (29.6%)	
Aspirin Alone	71 (17.9%)	93 (18.7%)	
Other	140 (35.3%)	161 (32.4%)	
More Than One	86 (21.7%)	96 (19.3%)	

N/A = Not Applicable

Table 3

DVT and Thrombosis Rates, Including and Excluding Post-Intervention COVID Patients (Column Percentages Shown)

			DVT Rate	Thrombosis Rate	DVT or Thrombosis Rate
BMH					
		Pre-Intervention	2 (1.6%)	0 (0.0%)	2 (1.6%)
	Incl. COVID	Post-Intervention	1 (0.6%)	0 (0.0%)	1 (0.6%)
	Excl. COVID	Post-Intervention	0 (0.0%)	0 (0.0%)	0 (0.0%)
LMC					
		Pre-Intervention	1 (0.6%)	4 (2.4%)	5 (3.0%)
	Incl. COVID	Post-Intervention	1 (0.5%)	1 (0.5%)	2 (1.0%)
	Excl. COVID	Post-Intervention	1 (0.6%)	1 (0.6%)	2 (1.3%)
PH					
		Pre-Intervention	1 (1.6%)	0 (0.0%)	1 (1.6%)
	Incl. COVID	Post-Intervention	0 (0.0%)	1 (1.5%)	1 (1.5%)
	Excl. COVID	Post-Intervention	0 (0.0%)	1 (1.8%)	1 (1.8%)
RH					
		Pre-Intervention	1 (2.7%)	0 (0.0%)	1 (2.7%)
	Incl. COVID	Post-Intervention	0 (0.0%)	1 (1.4%)	1 (1.4%)
	Excl. COVID	Post-Intervention	0 (0.0%)	1 (2.3%)	1 (2.3%)
System					
		Pre-Intervention	5 (1.3%)	4 (1.0%)	9 (2.3%)
	Incl. COVID	Post-Intervention	2 (0.4%)	3 (0.6%)	5 (1.0%)
	Excl. COVID	Post-Intervention	1 (0.3%)	3 (0.8%)	4 (1.1%)

Table 4

Patient Characteristics Associated with a DVT, Thrombosis, or DVT or Thrombosis (excluding COVID patients) (Row Percentages Shown)

	DVT		Thrombosis		DVT or Thrombosis	
	No (n = 750)	Yes (n = 6)	No (n = 749)	Yes (n = 7)	No (n = 743)	Yes (n = 13)
Patient Age, Mean (SD)	66.9 (15.6)	66.2 (16.3)	67.0 (15.6)	65.6 (19.8)	67.0 (15.6)	65.8 (17.5)
Patient Sex, n(%)						
Female	310 (99.4%)	2 (0.6%)	310 (99.4%)	2 (0.6%)	308 (98.7%)	4 (1.3%)
Male	440 (99.1%)	4 (0.9%)	439 (98.9%)	5 (1.1%)	435 (98.0%)	9 (2.0%)
Cancer Diagnosis, n(%)						
No	584 (99.3%)	4 (0.7%)	583 (99.2%)	5 (0.9%)	579 (98.5%)	9 (1.5%)
Yes	166 (98.8%)	2 (1.2%)	166 (98.8%)	2 (1.2%)	164 (97.6%)	4 (2.4%)
History of DVT or PE, n(%)						
No	660 (99.6%)	3 (0.5%)	656 (98.9%)	7 (1.1%)	653 (98.5%)	10 (1.5%)
Yes	90 (96.8%)	3 (3.2%)	93 (100.0%)	0 (0.0%)	90 (96.8%)	3 (3.2%)
Previous PICC, n(%)						
No	126 (100.0%)	0 (0.0%)	125 (99.2%)	1 (0.8%)	125 (99.2%)	1 (0.8%)
Yes	624 (99.1%)	6 (1.0%)	624 (99.1%)	6 (1.0%)	618 (98.1%)	12 (1.9%)

SD = Standard deviation

Table 5

PICC Characteristics Associated with a DVT, Thrombosis, or DVT or Thrombosis (Row Percentages Shown)

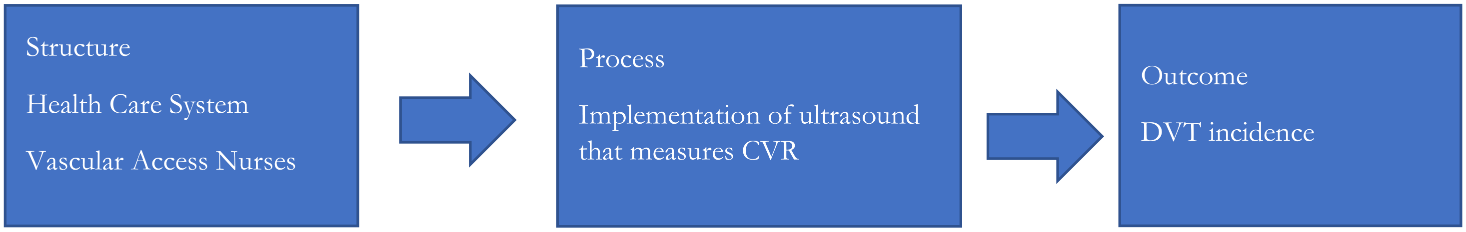
	DVT		Thrombosis		DVT or Thrombosis	
	No (n = 750)	Yes (n = 6)	No (n = 749)	Yes (n = 7)	No (n = 743)	Yes (n = 13)
PICC Gauge, n(%)						
3	1 (100.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)
4	219 (99.6%)	1 (0.5%)	218 (99.1%)	2 (0.9%)	217 (98.6%)	3 (1.4%)
5	530 (99.1%)	5 (0.9%)	530 (99.1%)	5 (0.9%)	525 (98.1%)	10 (1.9%)
PICC Location, n(%)						
Basilic	612 (99.4%)	4 (0.7%)	609 (98.9%)	7 (1.1%)	605 (98.2%)	11 (1.8%)
Brachial	121 (98.4%)	2 (1.6%)	123 (100.0%)	0 (0.0%)	121 (98.4%)	2 (1.6%)
Cephalic	17 (100.0%)	0 (0.0%)	17 (100.0%)	0 (0.0%)	17 (100.0%)	0 (0.0%)
PICC Side, n(%)						
Left	143 (98.6%)	2 (1.4%)	144 (99.3%)	1 (0.7%)	142 (97.9%)	3 (2.1%)
Right	607 (99.4%)	4 (0.7%)	605 (99.0%)	6 (1.0%)	601 (98.4%)	10 (1.6%)
PICC Side and Location, n(%)						
Left Basilic	102 (99.0%)	1 (1.0%)	102 (99.0%)	1 (1.0%)	101 (98.1%)	2 (1.9%)
Left Brachial	35 (97.2%)	1 (2.8%)	36 (100.0%)	0 (0.0%)	35 (97.2%)	1 (2.8%)
Left Cephalic	6 (100.0%)	0 (0.0%)	6 (100.0%)	0 (0.0%)	6 (100.0%)	0 (0.0%)
Right Basilic	510 (99.4%)	3 (0.6%)	507 (98.8%)	6 (1.2%)	504 (98.3%)	9 (1.8%)
Right Brachial	86 (98.9%)	1 (1.2%)	87 (100.0%)	0 (0.0%)	86 (98.9%)	1 (1.2%)
Right Cephalic	11 (100.0%)	0 (0.0%)	11 (100.0%)	0 (0.0%)	11 (100.0%)	0 (0.0%)
CVR, Mean (SD)[1]	31.0 (10.7)	41 (N/A)	31.0 (10.7)	30.7 (7.6)	31.0 (10.7)	33.3 (8.1)
< 20	51 (100.0%)	0 (0.0%)	51 (100.0%)	0 (0.0%)	51 (100.0%)	0 (0.0%)
20-35	168 (100.0%)	0 (0.0%)	166 (98.8%)	2 (1.2%)	166 (98.8%)	2 (1.2%)

36-45	129 (99.2%)	1 (0.8%)	129 (99.2%)	1 (0.8%)	128 (98.5%)	2 (1.5%)
> 45	9 (100.0%)	0 (0.0%)	9 (100.0%)	0 (0.0%)	9 (100.0%)	0 (0.0%)
Anticoagulant, n(%)						
None	204 (99.5%)	1 (0.5%)	199 (97.1%)	6 (2.9%)	198 (96.6%)	7 (3.4%)
Aspirin Alone	139 (100%)	0 (0%)	139 (100%)	0 (0%)	139 (100%)	0 (0%)
Heparin Alone	88 (96.7%)	3 (3.3%)	91 (100%)	0 (0%)	88 (96.7%)	3 (3.3%)
Lovenox Alone	78 (100%)	0 (0%)	78 (100%)	0 (0%)	78 (100%)	0 (0%)
Eliquis Alone	53 (98.2%)	1 (1.9%)	54 (100%)	0 (0%)	53 (98.2%)	1 (1.9%)
All Other Single Anticoagulants	26 (96.3%)	1 (3.7%)	27 (100.0%)	0 (0.0%)	26 (96.3%)	1 (3.7%)
Combination	162 (100%)	0 (0%)	161 (99.4%)	1 (0.6%)	161 (99.4%)	1 (0.6%)
Anticoagulant, n(%)						
None	204 (99.5%)	1 (0.5%)	199 (97.1%)	6 (2.9%)	198 (96.6%)	7 (3.4%)
Aspirin Alone	139 (100%)	0 (0%)	139 (100%)	0 (0%)	139 (100%)	0 (0%)
Other	245 (98.0%)	5 (2.0%)	250 (100.0%)	0 (0.0%)	245 (98.0%)	5 (2.0%)
More Than One	162 (100.0%)	0 (0.0%)	161 (99.4%)	1 (0.6%)	161 (99.4%)	1 (0.6%)

1. Post-intervention period only.

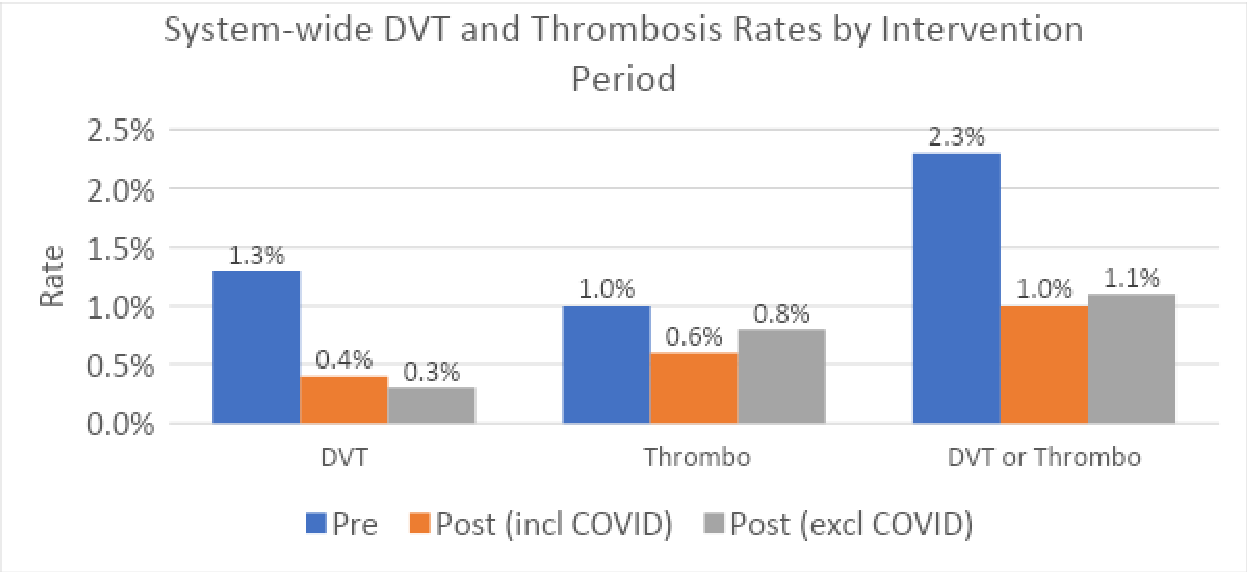
N/A = Not Applicable

Figure 1



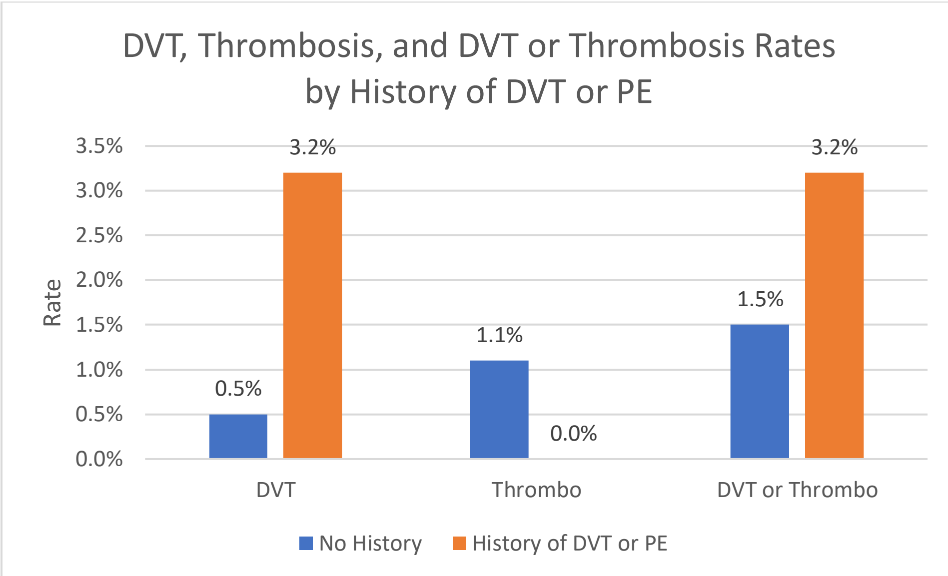
Correlation of Project Concepts to Donabedian Model for Quality of Care (NHS Improvement, 2018).

Figure 2



DVT and Thrombosis Rates by Intervention Period

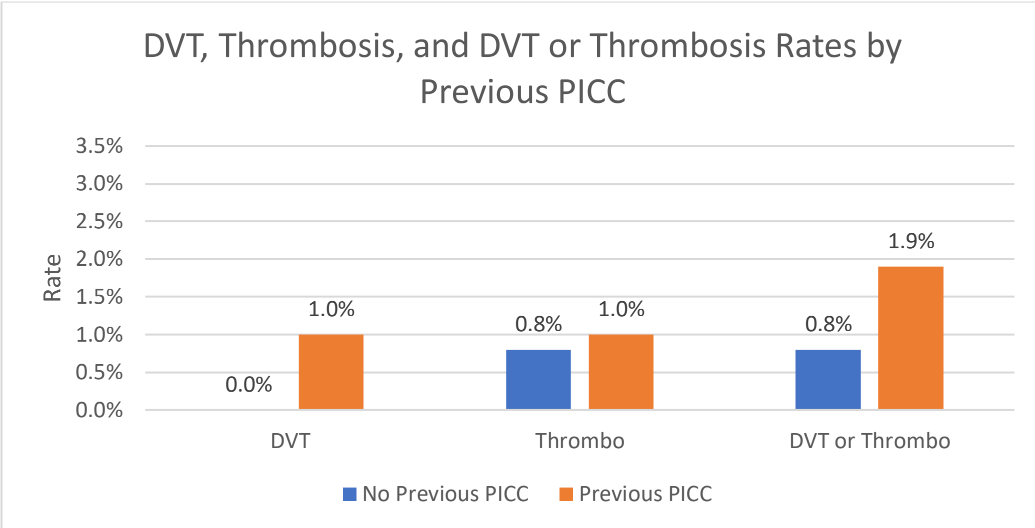
Figure 3



DVT, Thrombosis, and DVT or Thrombosis Rates by History of DVT or PE

*Excluding COVID patients

Figure 4



DVT, Thrombosis, and DVT or Thrombosis Rates by History of Previous PICC

*Excluding COVID patients

Appendix A

Main Line Health

OFFICE OF
RESEARCH PROTECTIONS

259 N. Radnor Chester Road
Suite 290
Radnor, PA 19087
TEL 610.225.6222
FAX 610.293.8202
mainlinehealth.org

September 2, 2020

Kristin Hartner
Bryn Mawr Hospital

RE: Catheter-related thrombosis (CRT) and Catheter-to-Vessel Ratio (CVR)

Dear Kristin:

We have reviewed the information you submitted to the Office of Research Protections (ORP) regarding the above referenced project. Based on the information you provided, the research project as submitted on September 2, 2020 is a Quality Improvement project and therefore does not require review by the Main Line Hospitals Institutional Review Board (MLH IRB).

In the future, if changes are made to the above referenced project, please notify the ORP immediately so a determination can be made if MLH IRB review is necessary at that time.

If you have any questions, please call the Office of Research Protections at 610-225-6222.

Sincerely,

Albert Keshgegian, M.D., Ph.D.
Chairman, Main Line Hospitals Institutional Review Board

Appendix B

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Protocol ID # 20201116D
This Protocol ID number must be used in all communications about this project with the IRB.

TO: Kristin Hartner

FROM: Nicole M. Cattano, Ph.D.
Co-Chair, WCU Institutional Review Board (IRB)

DATE: 11/15/2020

Project Title: Catheter to Vein Ratio and Catheter Related Thrombosis: Retrospective review of records

Notification of Initial Study Exemption Determination

☒**Exempt From Further Review**

This Initial Study submission meets the criteria for exemption per the regulations found at 45 CFR 46.104 (4)(ii). As such, additional IRB review is not required.

The determination that your research is exempt does not expire, therefore, annual review is not required and no expiration date will be listed on your approval letter. If changes to the research are proposed that would alter the IRB's original exemption determination, they should be submitted to the WCU IRB for approval, using the IRB application form (check off I.G. Revision).

Your research study will be archived 3 years after initial determination. If your Exempt study is archived, you can continue conducting research activities as the IRB has made the determination that your project met one of required exempt categories. The only caveat is that no changes can be made to the application. If a change is needed, you will need to submit a NEW Exempt application. Please see www.wcupa.edu/research/irb.aspx for more information.

However, it is very important that you *close-out your project when completed or if you leave the university*. Faculty mentors are responsible for oversight of student projects and should ensure exempt studies are completed and closed-out before the student leaves the university.

The Principal Investigator and/or faculty mentor is responsible for ensuring compliance with any applicable local government or institutional laws, legislation, regulations, and/or policies, whether conducting research internationally or nationally. Please contact the WCU Office of Sponsored Research and Programs at irb@wcupa.edu with any questions.

Sincerely,

Co-Chair of WCU IRB

WCU Institutional Review Board (IRB)
IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

West Chester University is a member of the State System of Higher Education

Appendix C

Sample Data Collection Form