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Individualizing Patient Care During Percutaneous Coronary Intervention to Reduce Operator Risk Adjusted Bleeding Rates: A Pre/Post Interventional Study

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Sarah Brown, Student

Dr. Sheila Melander, Advisor

Individualizing Patient Care During Percutaneous Coronary Intervention to Reduce Operator Risk Adjusted Bleeding Rates: A Pre/Post Interventional Study

Submitted in Partial Fulfillment of the Requirements for the Degree of Doctor of Nursing Practice at the University of Kentucky

By

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Abstract

OBJECTIVE: It is well documented that the most common problems associated with diagnostic and interventional angiography are major bleeding and vascular complications. While previous research and the American College of Cardiology (ACC) recommend the use of bleeding risk stratification tools, there is little evidence related to the use of bleeding avoidance strategies in the high-risk for bleeding population. This study aims to determine if individualizing access site and anticoagulation strategies based on bleeding risk stratification would positively impact NCDR Risk-Adjusted Bleeding Rates.

METHODS: This was a single-center pilot study utilizing retrospective chart reviews with pre/post design. Data was collected on all percutaneous coronary interventions (PCI) from 3 interventionalists excluding ST elevation myocardial infarction (STEMI) and staged chronic total occlusion (CTO) procedures. Variables analyzed in the study included age, gender, body mass index (BMI), bleeding risk score, access site, anticoagulation strategy, P2Y12 inhibitor used, use of GPIIbIIIa inhibitors, use of vascular closure devices, ultrasound use, bleeding events, blood transfusions and the previous diagnosis of heart failure, end-stage renal disease, and diabetes mellitus. The study compared baseline data (3 months prior to implementation) to post implementation data (3 months after implementation).

RESULTS: High bleeding risk patients comprised 14% and 18% of the baseline and post implementation groups respectively; after exclusion criteria was considered, only 9.4% and 10.7% of the PCI subjects were utilized for analysis. Sample sizes were too small to show statistically significant differences between the baseline and post implementation groups.

CONCLUSION: Further research is necessary to directly correlate the benefits of individualizing patient care based on bleeding risk stratification.

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Dedication

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Individualizing Patient Care During Percutaneous Coronary Intervention to Reduce Operator Risk Adjusted Bleeding Rates: A Pre/Post Interventional Study

Background

Peri-procedural bleeding is a serious risk for the percutaneous coronary intervention (PCI) patient population. Therefore, as Singh (2015) states, "recognition and mitigation of bleeding risk following PCI is a recognized health care priority" (p. 2233). Major bleeding and vascular complications are among the most common complications associated with diagnostic and interventional angiography (Nelson et al., 2018). Moreover, bleeding complications have long been cited as direct predictors of prolonged hospital stays, increased short and long-term morbidity and mortality, and significantly increased financial burden (Singh, 2015). Among other factors, predictors of major bleeding include patients who are of advanced age, female, or with renal impairment (Singh, 2015). Bleeding avoidance strategies (BAS) can be utilized to successfully improve quality of care in patients who are at high risk for major bleeding events. BAS include use of radial artery access rather than femoral artery when possible; use of bivalirudin rather and heparin with/without glycoprotein inhibitors; and the use of vascular closure devices after femoral access for PCI (Khambatta et al., 2016). The American College of Cardiology (ACC) clinical practice guidelines recommend that all patients be evaluated for bleeding risk prior to PCI (Levine et al., 2011). Bleeding risk scoring tools can be utilized to identify patients who are most at risk for major bleeding events and further individualize intra and post procedural care decisions to maximize patient safety (Kerl et al., 2015).

The National Cardiovascular Data Registries (NCDR) CathPCI registry monitors and can be used to draw conclusions regarding major bleeding events in cardiac catheterization labs nationwide. The CathPCI In-Hospital Risk Adjusted Rate of Bleeding (RAB) considers any post

PCI patient eighteen years or older with a post-PCI bleeding event. The ACC defines post-PCI bleeding as any of the following: a bleeding event within 72 hours (arterial access site bleeding; retroperitoneal, gastrointestinal, or genitourinary bleeding); intracranial hemorrhage; cardiac tamponade; post-procedure hemoglobin decrease of > 4 g/dl and pre-procedure hemoglobin of < 16 g/dl (Rao et al., 2013). As of 2017, a widely known cardiovascular institution in the Midwest remains above the national benchmark for this measure.

Multiple tools have been shown to be effective in predicting PCI bleeding risk. One validated tool used widely nationwide is the NCDR CathPCI Bleeding Risk Score. This simple tool was derived from the national CathPCI database, and can be used in patients who present with acute coronary syndrome (ACS) or those who are undergoing elective angiography (Singh, 2015). The NCDR Bleeding Risk Score considers the patient's presentation, status of ST elevated myocardial infarction (STEMI), age, body mass index (BMI), previous PCI, degree of renal dysfunction, presentation of shock, recent cardiac arrest, gender, and most recent hemoglobin result (Rao et al., 2013). Bleeding risk is calculated based on a point system and categorized (low, intermediate, or high) based on the result. This tool is currently utilized to evaluate all patients undergoing coronary angiography at the institution of interest for this study. Once bleeding risk stratification has been established, the operator and care team should utilize the information to improve patient safety. Data suggest that the employment of BAS in patients who are at intermediate or high risk for bleeding both improves the safety of the procedure for vulnerable populations and decreases costs associated with PCI.

Because the risk for bleeding is modifiable (Singh, 2015), it is crucial that intermediate and high risk patients be identified and treated accordingly. The purpose of this study is to utilize the Bleeding Risk Score to individualize arterial access and anticoagulation strategies to

decrease individual operator RAB rates. This is a small pilot study in which the investigator will follow three high volume physicians and compare their bleeding complication rates before and after employing the patient appropriate BAS. The question posed for this research is: What is the effect of using the NCDR CathPCI Bleeding Risk Score for individualized access site and anticoagulation strategies on individual operator RAB rate?

This project proposes the use of BAS in the patient populations deemed at high risk for bleeding events peri-procedure. Singh (2015) suggests considering the following for those who are at increased risk of bleeding: (1) use of radial access; (2) aiming for activated clotting time (ACT) levels; (3) use of bivalirudin for high risk cases; (4) use of fluoroscopy, ultrasound and micropuncture techniques to guide femoral access; (5) early sheath removal; and (6) use of vascular closure devices. The specific aim of this project is to provide evidence to determine if operator RAB rates are affected by employment of BAS. A secondary goal of this project is to begin a shift among operators in this environment to utilize the bleeding risk score made available to them to maximize patient safety. Applying evidence-based practice to the operator's normal routine may decrease overall bleeding complications, improve patient outcomes, and minimize financial costs associated with adverse bleeding events.

Theoretical Framework

The Transtheoretical Model (TTM; Stages of Change) formed the theoretical framework for this study. Applying the TTM helped us identify the stages of change that the operators faced while adapting to implement evidence-based practice. The focus was on utilizing tools that are readily available to optimize patient safety and minimize peri-procedural complications. Nelson et al. (2018) have discussed the operator preference of femoral access, the lack of use of adjunct imaging (fluoroscopy and ultrasound) for access, the minimal use of micropuncture needle kits,

and the preference of unfractionated heparin as opposed to bivalirudin. The authors further discussed the disconnect between evidence and practice in this area: experience and comfort with outdated techniques continue, though evidence clearly shows that a change is warranted (Nelson et al., 2018).

Review of Literature

Methods

Thorough searches of the PubMed and Scopus databases were completed to obtain current research on vascular access complications, strategies to avoid bleeding complications, use of bleeding risk predictor tools, and comparison of the use of heparin versus bivalirudin in the setting of coronary intervention. The inclusion criteria limited this literature review to studies and/or reviews published since 2013 to ensure that the most current and relevant literature was analyzed. Keywords and phrases such as "vascular access complications," "bleeding risk score," "prevention AND complications AND vascular," "coronary intervention," and "bivalirudin AND heparin" were all used for database search purposes. Several combinations of database search results were utilized to narrow search results further. The search for evidence yielded a high-quality mixture of randomized controlled studies, systematic reviews and meta-analyses. The search results were closely examined to include only the highest level of evidence, related specifically to identifying the high risk PCI population and strategies which can be employed to decrease vascular complications within this group.

Minimizing Major Bleeding Complications

Despite the equipment and technology advances associated with PCI procedures, peri-procedural bleeding remains one of the most common complications in this population (Gargiulo

et al., 2018; Khambatta et al., 2016; Mehran et al., 2010; Nelson et al., 2018; Numasawa et al., 2017; Rao, Chhatriwalla et al., 2013; Singh, 2015). More specifically, femoral artery access site bleeding and hematoma formation are the most common vascular complications associated with the procedure (Khambatta et al., 2016; Nelson et al., 2018; Pasala et al., 2016; Rashid et al., 2017). As more potent pharmacological treatment is introduced for prevention of thrombotic events peri-procedure, a consequence is increased hemorrhagic complications (Mehran et al., 2010). Bleeding complications following PCI have been correlated to higher patient morbidity and mortality, as well as prolonged hospitalization and increased costs (Dobies et al., 2015; Gargiulo et al., 2018; Khambatta et al., 2016; Mehran et al., 2010; Rao, Chhatriwalla et al., 2013; Rashid et al., 2017; Singh, 2015). Significant predictors of increased bleeding risk associated with PCI include older age, female gender, femoral artery access, low BMI, and renal impairment (Dobies et al., 2015; Gargiulo et al., 2018; Khambatta et al., 2016; Rao, McCoy et al., 2013; Singh, 2015). Utilizing BAS in patient populations who are at highest risk for bleeding events has been associated with decreased rates of bleeding complications (Khambatta et al., 2016; Mina, Gobrial, Modi, & Dominic, 2016; Nelson et al., 2018; Rao, Chhatriwalla et al., 2013; Singh, 2015).

Individualized Bleeding Risk Scoring Tools

Simple tools are available to assist providers in stratifying patients into groups based on the risk factors for increased bleeding events (Dobies et al., 2015; Kerl et al., 2015; Mehran et al., 2010; Rao, Chhatriwalla et al., 2013; Rao, McCoy et al., 2013). Various bleed risk stratification tools exist which utilize point systems for specific patient variables and determine that patient's level of risk for peri-procedural bleeding. These models are referred to as bleeding risk scores (BRS), and it is the NCDR PCI BRS that is most widely used throughout the United

States (Dobies et al., 2015; Kerl et al., 2015; Rao, Chhatriwalla et al., 2013; Rao, McCoy et al., 2013). The NCDR PCI BRS was derived from a logistic regression analysis utilized to determine the pre-PCI variables most predictive of bleeding in a PCI population of more than 300,000 (Kerl et al., 2015). The NCDR PCI BRS model has been updated as recently as 2013 to identify the most significant risk factors noted in contemporary clinical practice, making it a useful tool to guide clinical decision-making and support quality improvement (Kerl et al., 2015; Rao, McCoy et al., 2013).

Radial Versus Femoral Access

Radial artery access certainly decreases bleeding complications among the PCI patient population and its use is on the rise (Jaswaney et al., 2018; Khambatta et al., 2016; Mina et al., 2016; Rashid et al., 2017; Singh, 2015). In a large survey conducted in 2016, a great portion (42%) of cardiologists considered themselves both radialists and femoralists; however, it is important to note that some providers, as many as 18%, still strongly favor femoral access (Nelson et al., 2018). While the benefits of radial access are well known, femoral access is the preferred approach for patients with cardiogenic shock, left main or bifurcation PCI, and procedures with mechanical circulatory support (Nelson et al., 2018). Other patient populations in which operators preferred femoral access include end-stage renal disease, known chronic total occlusion (CTO), concurrent right heart catheterization, history of coronary artery bypass grafts (CABG), need for rotational atherectomy, and an anticipated need for a sheath larger than 6F (Nelson et al., 2018).

Useful strategies for decreasing bleeding complications associated with transfemoral access include: the routine use of a bleeding risk stratification tool, radial access if possible, lower activated clotting time (ACT) goals, use of bivalirudin for high-risk bleeding scores,

judicious and selective use of glycoprotein inhibitors, use of fluoroscopy, ultrasound and micropuncture needle when gaining femoral access, early sheath removal and the use of vascular closure devices (Kerl et al., 2015; Mehran et al., 2010; Nelson et al., 2018; Pasala et al., 2016; Rashid et al., 2017; Singh, 2015). However, Nelson et al. (2018) found in their 2016 survey that, despite best practice guidelines, 60% of the respondents preferred to use palpation alone when gaining femoral artery access, only 28% utilized fluoroscopy, and only 12% reported using ultrasound guidance (Nelson et al., 2018). Furthermore, Nelson et al. (2018) reported that two-thirds of their respondents indicated that they never use micropuncture needle kits, a very small needle which reduces trauma to the artery, when gaining transfemoral access (Murarka and Movahed, 2014).

Antithrombotic Therapy in Percutaneous Coronary Intervention

Both elective PCI procedures and those in the setting of ACS are associated with a high risk of thrombotic complications (Chaudry et al., 2018; Gargiulo et al., 2018; Grajek et al., 2018; Jaswaney et al., 2018; Mina et al., 2016). Evidence of the most effective pharmacotherapy to successfully reduce thrombotic complications while minimizing the risk of bleeding complications remains ambiguous. Antithrombotic therapy continues to evolve with newer, more potent medications available on the market and the measuring and comparing of these pharmacological strategies are further complicated by the evolution of drug-eluting coronary stents. Current best practice guidelines include both the use of heparin and bivalirudin for prevention of stent thrombosis and subsequent infarction; however, the clinical safety regarding hemorrhagic effects of these therapies is conflicting (Gargiulo et al., 2018; Grajek et al., 2018; Jaswaney et al., 2018; Kerl et al., 2015; Mina et al., 2016; Nairooz et al., 2014; Pasala et al., 2016; Saad et al., 2017; Shah et al., 2016). The clinical decision of treatment with heparin versus

bivalirudin has long been debated. Bivalirudin has been shown to be more efficient at preventing bleeding complications associated with PCI; however, there is conflicting evidence that there may be small, but possibly clinically significant, increase in thrombotic events (Gargiulo et al., 2018; Jaswaney et al., 2018; Kerl et al., 2015; Mina et al., 2016; Pasala et al., 2016). Conversely, heparin appears to be sufficiently effective in preventing thrombotic events and has a significant financial advantage, but it has been associated with increased bleeding complication rates (Chaudry et al., 2018; Gargiulo et al. 2018; Jaswaney et al., 2018). Historically, several major trials have provided conflicting support for both bivalirudin and heparin, prompting major swings in clinical use of each. Currently, evidence is mounting that supports the use of bivalirudin specifically in high risk patient subsets to sufficiently prevent thrombotic events while mitigating the increased bleeding risk.

Bivalirudin Use in High Risk Patient Subsets

Recent literature supports the use of bivalirudin when patients are identified as high risk by the NCDR PCI BRS *and* access will be gained via femoral artery (Kerl et al., 2015; Pasala et al., 2016; Singh, 2015). However, it is important to understand that there is no benefit to using bivalirudin in procedures where radial access is utilized, even when the patient is identified as "high risk" by bleed risk stratification tools (Mina et al., 2016; Pasala et al., 2016).

Agency Description

Setting

The study took place in the Cardiac Cath Lab of a 555-bed acute care hospital located in the Midwest. The unit has five Cath Lab suites with varying patient volume in each room, each day. The Cath Lab management team consists of a manager, assistant manager, and three

coordinators. The lab is staffed by 21 nurses and 15 radiology technologists and there are 10 interventional cardiologists who practice in this environment. This lab completed 3251 left heart catheterizations in 2019, with 1529 of those proceeding to PCI.

Target Population

The target population for this study is all patients undergoing PCI at this facility. The study sample included PCI patients from three high volume physicians. Post implementation, the physicians based their access approach and anticoagulation on the BRS, which is calculated pre-procedure and included in the Safety Time-Out. Operators were asked to plan radial access when possible for patients who are considered high risk for bleeding complications (BRS 65 or greater). If access was gained via femoral artery and the procedure proceeded to angioplasty, the physician was asked to choose bivalirudin for anticoagulation therapy in the high risk bleeding score population.

Congruence with Institution's Mission/Vision

The vision statement of the institution describes being a national leader of personalized patient experiences, clinical outcomes and affordable care. The institution's mission statement includes "providing exceptional outcomes and the finest experiences." It is important to note the hospital's initiative to provide personalized health care, as this is precisely where this study's aim is focused; individualizing access site and anticoagulation decisions based on specific patient characteristics and presentation.

Stakeholders and Their Roles

Stakeholders of this research included patients at high risk for bleeding and their families, Cath Lab staff, pre-procedural nursing staff, interventional cardiologists, pharmacy staff, Cath

Lab administration, and hospital administration. Patients presented for an elective, urgent or emergent cardiac catheterization and expected care to be personalized based on their needs. Patients who are at increased risk of bleeding can avoid major complications which are often associated with longer hospital stays, additional diagnostic testing, blood transfusions or subsequent procedures/surgeries. Patients' families also had a stakeholder role, as families are often secondarily affected by longer hospital stays, increased financial responsibilities, increased care requirements, and subsequent follow-up care appointments or procedures. Pre-procedural nursing staff played an important role by completing the BRS calculator accurately and in a timely manner. Clear understanding of the bleeding risk scoring tool was essential. Accuracy was particularly important, as scoring one factor incorrectly could result in the patient being stratified in an inappropriate risk category. Nursing staff within the Cath Lab played a significant role by identifying the high risk for bleeding population and collaborating with the physician regarding access site intention and anticoagulation strategy if the patient were to need PCI.

Interventional cardiologists were a key stakeholder in this process, as the decisions to individualize patient care based on bleeding risk stratification lay with them. Their personal RAB rate could be greatly impacted by a simple change in practice, making them more proficient in practice with fewer complications associated with their procedures. Pharmacy staff had an important role as well, as the use of bivalirudin was low prior to this project, and could have increased with this research study. It was important for the study to maintain an adequate supply of bivalirudin readily available in the Cath Lab suites. The Cath Lab administration was an important stakeholder for this research study as well: it was important for them to maintain the highest level of safety for the patients in this environment. With bleeding complications being

one of the most common life-threatening problems associated with this type of procedure, it was essential to mitigate the risk. Another important stakeholder for this research was the hospital administration. This is a relatively small private hospital which could be significantly affected by increased financial responsibility, significantly increased length of stay, and poor patient outcomes associated with bleeding complications.

Barriers and Facilitators

Barriers are factors that prevent change from being successfully implemented. For the purpose of this research major barriers included: (1) operator access site preference (2) increased cost of bivalirudin, (3) anatomical barriers to radial access site, (4) patient allergy listed to bivalirudin, (5) physician resistance, and (6) provider and nurse education.

Facilitators are factors that enhance successful implementation of change. For this research, facilitators included: (1) the fact that BRS had previously been implemented at this facility and was currently being used; (2) the fact that BRS was already included in the pre-procedure Safety Time-Out; (3) physician interest in decreasing publicly reported complication rates; (4) nurse interest in providing optimal patient care and outcomes; (5) administrative interest in providing safe, effective, and financially responsible care; and (6) the fact that patient data were already extracted in the CathPCI registry database.

Project Design

This pilot study involved a retrospective chart review with a pre/post design aimed at decreasing CathPCI Registry calculated RAB rates associated with PCI in a Midwestern acute care hospital. This research had several specific aims: (1) determine if RAB rates are positively impacted by specifically identifying high risk bleeding patients and taking appropriate bleeding

precautions; (2) assess pre and post intervention prevalence of radial access use in the high bleeding risk population; (3) assess pre and post intervention anticoagulation strategies used; (4) assess physician reported barriers to optimizing bleeding reduction strategies; (5) assess the comorbidity burden by analyzing the impact of previously diagnosed diabetes mellitus, heart failure, end-stage renal disease, and obesity when bleeding events occur in the high risk bleeding population.

Project Methods

Evidence-Based Intervention

Study physicians were asked to base access site decision and anticoagulation strategy on the patient's calculated risk of bleeding. Radial access was preferred in all patients with a high NCDR CathPCI BRS. Patients with a high BRS who were not candidates for radial access (anatomically unattainable, procedures requiring large bore catheters, or by choice), received bivalirudin, unless contraindicated, as opposed to unfractionated heparin for anticoagulation.

Procedures

The NCDR CathPCI BRS (Table 1) is calculated by the pre-procedure area on all patients who undergo cardiac procedures at this institution. To ensure accuracy, the procedure circulating nurse re-calculated the BRS for all patients who received care from the study interventionalist. Access site strategy was to be planned considering the patient's BRS: radial access when at all possible for patients considered high risk of bleeding. Patients with a known left internal mammary bypass graft were considered for access via left radial artery. For patients who were undergoing right and left heart catheterizations; radial/brachial, radial/internal jugular, radial subclavian or even radial artery/femoral vein were preferred to femoral artery access. If a

patient's upper extremity arterial anatomy was unfavorable, or the provider anticipated using large bore equipment, femoral artery access was used. If it was deemed necessary to access the femoral artery in a patient with a high BRS, the interventionalist was asked to utilize bivalirudin for anticoagulation if PCI was necessary (Figure 1).

The Cath Lab nursing staff was asked to complete a brief survey (Figure 2) on every patient who had a procedure completed by the study interventionalists. The survey was utilized to provide qualitative feedback regarding physician reported barriers to the process but was also designed to prompt nursing staff to consider the appropriate actions for high risk patients.

IRB Approval Process

Institutional Review Board (IRB) approval was obtained from both the University of Kentucky Medical Center and the study institution. The University of Kentucky's Office of Research Integrity approved the project via an expedited review process; informed consent was waived. Subsequently, the project gained approval at the institution through the process of an IRB Reliance Agreement.

Implementation

Baseline data collection occurred from September 1st, 2019 through November 30th, 2019. Education of both the study interventionalists and the Cath Lab nurses occurred in November 2019. Post implementation data were collected from December 1st, 2019 through February 29th, 2020.

Education began with a thorough discussion with the three study physicians regarding the purpose and implications of the study and the decision tree for patients deemed at high risk for bleeding events according to the NCDR CathPCI BRS. One on one teaching was completed

with each registered nurse in the Cath Lab regarding the need for BRS calculation confirmation and its implications. Nurses were asked to address access site and potential anticoagulation strategy with the study physician prior to the start of the procedure. In addition, nurses were asked to complete a brief information survey for each case completed by the study interventionalists.

Sample

The sample included all patients who underwent PCI performed by the pilot study interventional cardiologists from September 1st, 2019 to February 29th, 2020. All PCIs are recorded in the CathPCI Registry; data from all the study physician cases were extracted for analysis. The study excluded all patients who were considered STEMI and patients who were staged for CTO procedures.

Measures and Instruments

Data collection was completed via NCDR CathPCI Registry data extraction and chart reviews by the investigator. Appropriate subjects (PCIs performed by the study interventionalists) were identified from the registry database. Variables that were included and extracted from the database consisted of: medical record number, gender, age, arterial access site, acute coronary syndrome, bleeding event, blood transfusion, the use of a vascular closure device, and presence of diabetes mellitus, heart failure, or end-stage renal disease. Variables which were manually extracted from medical chart review included: NCDR PCI BRS, intra-procedure anticoagulation, P2Y12 inhibitor used, use of GPIIbIIIa inhibitors, and the use of ultrasound for femoral access. Surveys completed by the Cath Lab nursing staff were reviewed by the investigator when the study time frame was completed. Data analysis was completed

utilizing SPSS data analytic software. Chi square testing was completed to compare variables between the baseline and post implementation data.

Results

Sample Characteristics

The baseline data consisted of 106 PCIs among the three study operators. Of the baseline data PCIs, 15 were considered high risk per the risk stratification procedure. There were 29 CTO procedures and 4 STEMIs, which were excluded. Subsequently, only 10 patients could be used for data analysis after excluding CTO and STEMI (Table 2).

In the post implementation time frame, there were 56 PCIs among the three interventionalists, and this group included 10 high bleeding risk patients. The post implementation data set had 18 CTOs and 5 STEMIs which were excluded from data analysis. Ultimately, 6 patients were included for data analysis (Table 2).

Of the patients in the baseline data, there were two bleeding "events" as classified by the NCDR CathPCI Registry, and three patients received blood transfusions; however, these patients were excluded from the data analysis due to exclusion criteria. Among the patients in the post implementation data set, there were two with bleeding events, of which one received a blood transfusion; however, one was excluded due to CTO procedure and the other was not a high risk patient. Consequently, no bleeding events or blood transfusions were recorded on patients who were used in data analysis in either group.

Despite the difference in PCI sample size variation, it is significant to note that the inclusion sample was a similar proportion in each group. Of the 106 baseline data PCIs, 10

patients were used (9.4%); of the 56 post implementation PCIs, 6 patients were used for data analysis (10.7%).

Sample Demographics

Demographics that were evaluated for this study included age, gender, and BMI. Ages of subjects in the baseline group ranged from 66 to 84 years old; ages in the post implementation group ranged from 60 to 91 years old. In the pre-implementation group 9 out of 10 (90%) were female, whereas in the post implementation group 2 of 6 (33%) were female. BMIs recorded in each group were similar. Subjects with BMI between 20-30 comprised 60% and 50% of the pre and post samples respectively; BMI between 30-40 included 30% and 33%; and BMI of 40+ consisted of one patient in each sample,10% and 16.7% respectively.

Risk-Adjusted Bleeding Rate

Among the patients who were considered at high risk for bleeding and included in the data analysis, there were no bleeding events recorded. The RAB rate is calculated with the number of bleeding events as the numerator. Due to the lack of bleeding events in the small sample analyzed, it is difficult to draw any conclusions regarding the RAB rate.

Comorbidities

Comorbidities that were analyzed in this study included heart failure, diabetes mellitus, and end-stage renal disease. These were included based on inclusion criteria of the NCDR CathPCI Registry. Of the subjects in the baseline data, 50% had heart failure, 50% had diabetes mellitus, and none met the end-stage renal disease criteria. Likewise, in the post implementation group, 50% had heart failure and 50% had diabetes mellitus; however, 2 patients (30%) did have end-stage renal disease.

Bleeding Avoidance Strategies

The BASs that this study examined included the use of radial artery access, the use of ultrasound when gaining femoral access, and the use of closure devices when femoral access was utilized. Radial access was used in 30% of cases in the baseline data compared with 16% of cases in the post implementation group. Ultrasound was utilized when gaining femoral access in 100% of the cases examined in both groups. The use of femoral artery closure devices increased after implementation; 29% and 40% in the baseline and post implementation groups, respectively.

Pharmacological Strategies

The study analyzed three pharmacological strategies: intra-procedural anticoagulation, P2Y12 platelet inhibitor choice, and the use of GPIIbIIIa inhibitors. Heparin was used for anticoagulation in 100% of subjects in the baseline data; bivalirudin was used in one of five femoral cases (20%) post implementation. Ticagrelor was the P2Y12 platelet inhibitor of choice in the baseline group and was used in 80% of the cases; clopidogrel usage increased post implementation and was used 67% of the time. GPIIbIIIa inhibitors were used less frequently in the post implementation group (17%) compared to the baseline group (40%).

Physician Reported Barriers

Barriers to applying BAS were assessed utilizing a survey which was completed by the circulating nurse. Patient history of CABG was cited as the most common barrier to utilizing radial artery access. Another frequently cited barrier to radial artery access was end stage renal disease with the presence of or anticipation of dialysis grafts or fistulas in the upper extremities.

Other barriers noted on the nurse completed survey included advanced age and previous radial access difficulties documented.

Discussion

The sample sizes of both the baseline and post implementation groups were too small to show statistically significant levels of change post implementation. Aside from gender, the demographics compared among the two groups were very similar, as was the measured comorbidities. Because female gender increases the bleeding risk score, it was anticipated that there would be more females than males in the high risk subset. The post implementation group had fewer females proportionately; however, there was more end-stage renal disease, which likely contributed to the shift.

There were no bleeding events recorded in either high-risk group, making it difficult to draw any conclusions associating individualized access site and anticoagulation strategies with decreased bleeding events. When considering the entire group of PCIs completed by the study interventionalists, there were two bleeding events recorded in the pre-implementation group: one which was stratified as high risk but presented as a STEMI and therefore was excluded, and another which was stratified as intermediate bleeding risk but was also a staged CTO procedure, which was an exclusion criterion as well.

This study specifically suggested the use of radial access and use of bivalirudin if PCI is performed via femoral access in the high bleeding risk population. Again, small sample sizes limit the significance of the findings. Radial access decreased proportionately post implementation. While this initially appears discouraging, feedback from the nurse survey indicated that three of the six patients were either hemodialysis patients with grafts or fistulas in

upper extremities, or peritoneal dialysis patients in which upper extremities are often preserved for the possibility of future upper extremity dialysis access placement. One of the six subjects in the post implementation group were accessed radially. One of the five post implementation subjects who was accessed via femoral artery did receive bivalirudin as opposed to heparin for anticoagulation, and it was specifically documented in the procedural report that bivalirudin was chosen due to the high bleeding risk.

There were encouraging secondary findings related to bleeding avoidance and anticoagulation strategies. The operators who participated in this study have excellent habits of utilizing ultrasound for femoral artery access. Ultrasound use was documented in 100% of all femoral PCI cases in both the baseline and post implementation data sets. Although the sample sizes are too small to be statistically significant, there was an increased use of femoral vascular closure devices. It is also important to note the decrease in GPIIbIIIa inhibitors and the increased use of clopidogrel as opposed to ticagrelor.

Implications for Future Nursing Research

The results of this study suggest several implications for the future of research on this topic. First, it would be important to expand data collection to increase high bleeding risk sample sizes. If continuing with one institution, there are multiple ways one could increase inclusion criteria to capture more high risk subjects. Expanding to include diagnostic procedures would give helpful insight to operator bleeding avoidance habits with the exception of anticoagulation strategies. Including all interventional cardiologists, CTO procedures, STEMI cases, and collecting data over longer periods of time are all suggestions to increase inclusion for a single center study. Another expansion opportunity in future research is the inclusion of intermediate bleeding risk patients. Singh (2015) discusses the importance of mitigating

bleeding risk with BAS in both the intermediate and high-risk populations; however, it is important to note that current research does not suggest the use of bivalirudin in the intermediate risk population.

To encourage and measure the use of bleeding avoidance strategies, researchers might also consider focusing on one strategy at a time with all interventional cardiologists in a single center. Perhaps evidence-based education for all interventionalists and staff on one bleeding avoidance focus point and monitoring that variable for a period would be more influential.

The institution where this study took place has, since implementation, shifted from measuring bleeding complications with RAB rates to monitoring bleeding events by capturing patients who have received blood transfusions post procedure. With this new technique, the institution does not rely on the NCDR CathPCI Registry bleeding event criteria; instead, they are investigating all patients who receive post procedure transfusions. Future research could include examining these post procedure transfusion cases to determine if the bleeding risk stratification tool is capturing the patients who require blood transfusions as high risk.

Limitations

This study had numerous limitations. The study was a pilot study completed at a single center, which limited the sample size. The nature of the high bleeding risk subset the study aimed to investigate narrowed the sample size for data analysis dramatically. The data were collected over a short period of time, further limiting the sample size. During the post implementation phase of the data collection, one interventionalist stepped away from the Cath Lab environment, adding an additional challenge to the sample size. Small sample sizes limit the ability to find significance and generalize findings in these data.

Again, the lack of bleeding events among the high risk patients analyzed limits the ability to draw any conclusions regarding individualized access site and anticoagulation strategies to decrease bleeding events.

Conclusion

Bleeding and vascular complications are potentially preventable and have significant consequences. The ACC recommends using risk stratification tools to identify patients at high bleeding risk and strategies to decrease access site complications have been thoroughly studied. Bleeding avoidance strategies that have the potential to impact patient outcomes are readily available and are inexpensive when compared to potential complications, yet they require behavior and strategy modifications among interventional cardiologists.

The aim of this study was to determine if individualizing patient care according to their bleeding risk stratification would be beneficial in preventing bleeding complications associated with PCI. While this study was able to provide insight into the high bleeding risk population, its proportion among PCIs, and its characteristics, small sample size limited its ability to reach significant conclusions related to its objectives. Further research is necessary to directly correlate the benefits of individualizing patient care based on bleeding risk stratification. Through the continued study of this patient population we can continue to provide individualized evidence based practice for high bleeding risk patients.

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Table 1: NCDR CathPCI Bleeding Risk Score

STEMI	No 0	Yes 15		
Age	< 60 0	60-70 10	71-79 15	> 80 20
BMI	< 20 15	20-30 5	31-39 0	≥ 40 5
Previous PCI	No 10	Yes 0		
Chronic Kidney Disease	No 0	Mild 10	Moderate 25	Dialysis 30
Shock	No 0	Yes 35		
Cardiac arrest within 24 hour	No 0	Yes 15		
Female	No 0	Yes 20		
Hb	Hb < 13 5	13 ≤ Hb < 15 0	Hb ≥ 15 10	
PCI Status	Elective 0	Urgent 20	Emergency/Salvage > 40	
Bleeding Risk (Total)	< 25 Low	25-65 Intermediate	> 65 High	

Table 2: Sample Characteristics

	Pre	Post
Total PCI	**106**	**56**
High Risk (all)	15	10
CTO (Excluded)	29	18
STEMI (Excluded)	4	5
High Risk excluding CTO & STEMI	**10**	**6**
Bleeding Events	**0**	**0**

Figure 1: High Risk Access Site and Anticoagulation Strategy

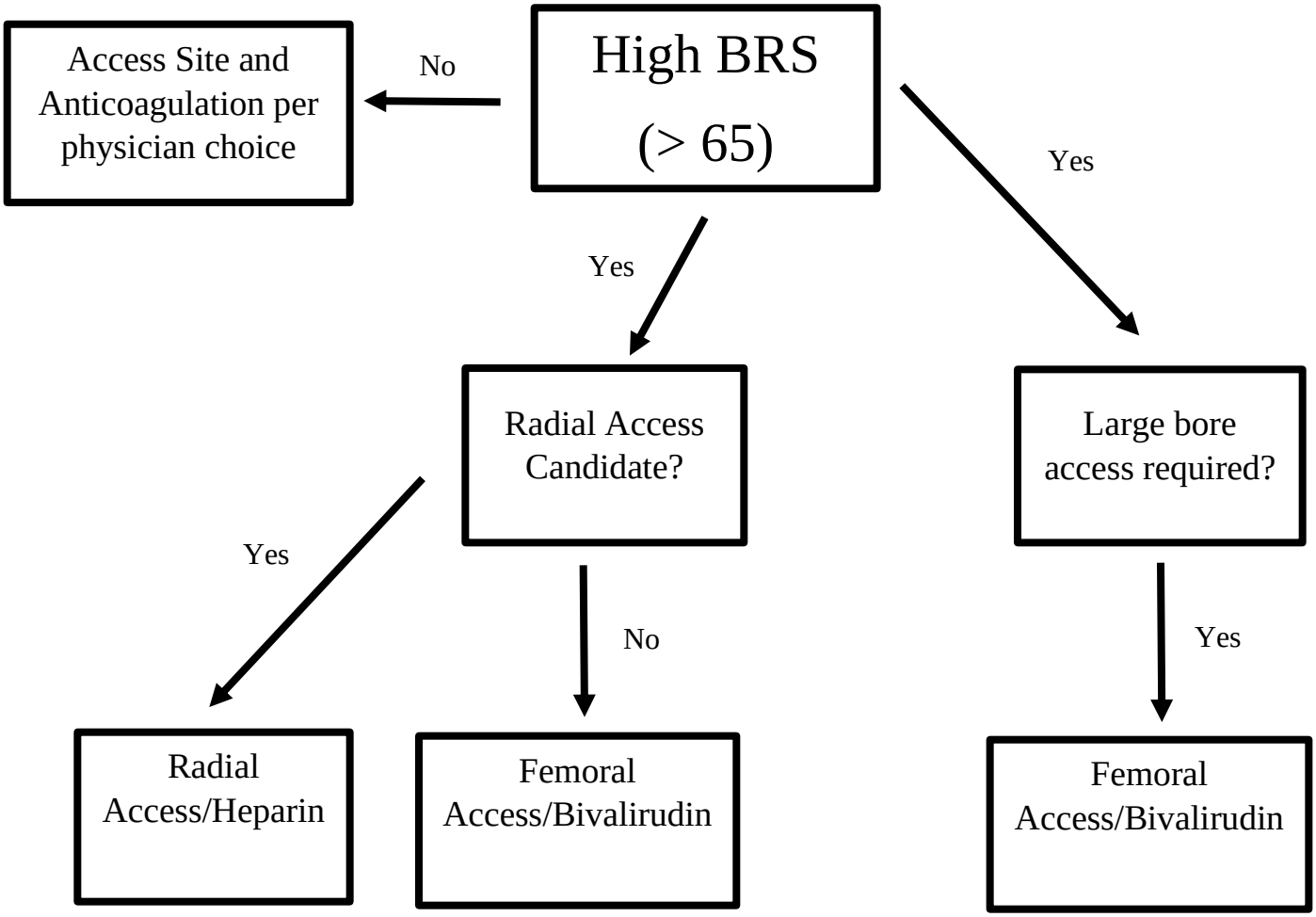

Figure 2: RN Data Collection Form

High Bleeding Risk? (if no, stop here)

Yes No

Radial Approach?

Yes No

If not radial, was bivalirudin (Angiomax) utilized for PCI?

Yes No N/A

Barriers to radial approach (if not utilized)?

_____

Any known bleeding complications at the conclusion of the case?

Yes No

Brief Description _____