Implementation of a Risk Assessment Tool in the Cardiac Catheterization Laboratory to Identify High Bleeding Risk Patients on DAPT after PCI: A Quality Improvement Project

by

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Abstract

Bleeding is a risk among patients on dual antiplatelet therapy (DAPT) after the percutaneous intervention (PCI) in acute coronary syndrome (ACS). There is a need to accurately identify the patients with increased bleeding risk. Evidence shows that 1.7 cases bleed among 100 PCI patients, and 5% of patients are re-admitted for bleeding which increases subsequent death or MI within 60 days post-discharge bleeding. Evidence suggests that the internally and externally validated BLeeMACS bleeding risk instrument can be used to measure bleeding risk in this population. This quality improvement project aims to improve the awareness among healthcare providers of the bleeding risk of individuals on DAPT undergoing PCI, using the BLeeMACS bleeding assessment tool. The databases PubMed, CINAHL, Cochrane Library, and Google Scholar were used to explore the most current relevant evidence. Nineteen publications met the inclusion criteria and were selected for literature review. Kurt Lewin's Theory of Planned Change was the Theoretical Framework to guide this project. The intervention sought to provide an educational session with cardiologists, advanced practice nurses, and physician assistants working in the cardiac catheterization laboratory. Pre- and post-surveys were used to evaluate the education session. Statistical analysis was done using the paired t-test. This project aimed to improve the awareness among healthcare providers of the bleeding risk of individuals on DAPT undergoing PCI.

Key Words: Post PCI bleeding; ACS-complication; assessment tools post-PCI; predicting the risk of bleeding in ACS.

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Introduction

Heart disease is the leading cause of death in the United States, and greater than 30 million adults are diagnosed with heart disease (CDC, 2020). Coronary Artery Disease (CAD) is a heart disease condition that contributes to myocardial ischemia (CDC, 2020). Every 40 seconds, someone has a myocardial infarction in the United States, and each minute, at least one person dies from a Myocardial Infarction (MI). The estimated cost of managing care for the individuals with Myocardial Infarction in the United States is approximately $219 billion each year (CDC, 2020). Every year, approximately 805,00 Americans die from an MI. Percutaneous Coronary Intervention (PCI) is performed to treat acute coronary artery disease (CAD). Acute coronary syndrome is a family of disorders sharing a similar pathogenic mechanism involving rupture of a vulnerable coronary atherosclerotic plaque. Exposure of the plaque contents to the circulating blood pool triggers vasoactive substances, leading to platelet activation and activation of the coagulation cascade. The extent of resultant platelet aggregation, thrombosis, vasoconstriction, and microembolization cause the syndrome's clinical manifestation (Vincent et al., 2017). The acute coronary syndrome includes ST-segment myocardial infarction (STEMI), Non-ST segment myocardial infarction (NSTEMI), and unstable angina (UA). ST-segment elevation myocardial infarction (STEMI), and Non-ST segment elevation myocardial infarction (NSTEMI) are treated by the percutaneous coronary intervention (PCI) accompanied by guideline-driven dual antiplatelet therapy (Dechant, 2016). When an individual undergoes a PCI, dual antiplatelet therapy is prescribed to avoid stent thrombosis. The American College of Cardiology (ACC) and American Heart Association (AHA) have existing guidelines in place that

detail the duration of dual antiplatelet therapy (DAPT). According to those guidelines, a Class I recommendation in most clinical settings is for at least 6-12 months DAPT after Percutaneous intervention (PCI). A Class IIb recommendation is made for prolonged DAPT beyond 12 months (Levine et al., 2016).

The PCI is associated with risks, including bleeding (from the access site, gastrointestinal, and intracranial), epistaxis, bruising, hematoma, and pseudoaneurysm. Approximately one in 20 individuals post-PCI are readmitted for bleeding, and most cases occur within 30 days of hospital discharge. These individuals are at increased risk for subsequent death or MI, especially within the first 60 days after a bleeding-related hospitalization (Valle et al., 2016). The most significant determinants of post-discharge bleeding are a history of bleeding, peripheral vascular disease, chronic obstructive pulmonary disease, oral anticoagulants, and age of more than 80 years (Ismail et al., 2019).

Bleeding is assessed by physical examination of the patient, laboratory findings (hemoglobin), and the use of a bleeding risk assessment tool. The bleeding risk assessment tool is crucial to consider because it negatively affects patient outcomes by increasing hospital admissions, cost of treatment, morbidity, and mortality. For the geriatric population, bleeding is especially important to avoid due to complex coronary disease, increased ischemia, physical disabilities, and frailty. Each year, 17.9 million people with cardiovascular disease die, most of them are elderly. Cardiovascular disease is the main cause of loss of quality of life and dependency among the elderly who represent a growing population segment (Riobóo-Lestón et al., 2019).

Bleeding is recognized as an important clinical event with a prognostic impact approximating coronary thrombosis. The magnitude of mortality risk after an episode of bleeding

is equal to that of myocardial infarction. There is a need to accurately identify the patients with increased bleeding risk (Baber, 2017). There are at least six bleeding risk assessment tools to-date. Bleeding risk assessment tools predict long-term bleeding risk in patients taking antiplatelet therapy in several tools: REACH, Dutch ASA Score, DAPT, PARIS, PRECISE-DAPT, and BLeeMACS. Among these risk assessment scores, the DAPT, PRECISE-DAPT, PARIS, and BLeeMACS have been assessed in the patient population who had acute coronary syndrome and underwent percutaneous coronary intervention. Advanced age is a variable common to all these measures. Also, baseline anemia was noticed to be one of the strongest independent predictors of bleeding mentioned in PARIS, Dutch ASA, PRECISE-DAPT, and BLeeMACS scores but is not assessed in REACH and DAPT measures. The risk assessment prediction scores show heterogenicity because different variables were assessed in these scores using different definitions among the different populations. However, in BLeeMACS, the variables used are more comprehensive and evidence based. These variables are independently associated with the bleeding risk as well. These variables include old age, renal impairment, vascular disease, hypertension, history of previous bleeding, malignancy, and serum hemoglobin. The risk score was externally validated using 96, 239 PCI patients and 93,150ACS patients without PCI, and was also internally validated in 4,651 patients randomly selected after dividing the BLeeMACS population into these two groups (Raposerias-Roubin et al., 2018).

Significance of the Problem

It is estimated that more than one million individuals undergo percutaneous coronary intervention (PCI) each year in the United States (Shuvy et al., 2014). Primary PCI, an early complete, timely, and sustained reperfusion after myocardial infarction is carried out in a cardiac catheterization laboratory after a loading dose of Aspirin and P2Y12 inhibitor therapy such as

clopidogrel, prasugrel, or ticagrelor (dual antiplatelet therapy) (Vincent et al., 2017). DAPT is a cornerstone pharmacological intervention after simple or complex coronary artery syndrome. treated with percutaneous intervention (Riobóo-Lestón et al., 2019). Dual antiplatelet therapy ensures more intense platelet inhibition than single treatment (Levine et al., 2016). Aspirin remains the drug of choice for secondary prevention of patients with stable coronary artery disease. Still, dual antiplatelet therapy combining aspirin (cyclooxygenase-1 inhibitor) with clopidogrel, prasugrel, or ticagrelor (Platelet adenosine diphosphate receptor inhibitor) plays a central role in the short-term and long-term management after complex coronary artery disease. Dual antiplatelet therapy has been shown to decrease recurrent major ischemic episodes in patients with acute coronary syndrome (ACS) or patients undergoing percutaneous intervention (PCI), including angioplasty and stent placement (Degrauwe et al., 2017).

The dual antiplatelet therapy has an increased incidence of post PCI bleeding. Significant bleeding occurs at a rate of 1.7%, mainly from the access site and gastrointestinal tract (Shuvy et al., 2014). Approximately 5 % of patients are readmitted for bleeding after PCI, with the highest incidence in the first 30 days of discharge. These patients are at increased risk for subsequent death or MI within the early 60 days after post-discharge bleeding (Valle et al., 2016).

Patients at risk of bleeding are older with more comorbid conditions such as Diabetes Mellitus (DM), chronic kidney disease (CKD), and Heart Failure (HF). Increasing age with comorbid conditions is associated with the increased bleeding incidence in patients on DAPT after PCI (Valle et al., 2016). American Heart Association and American College of Cardiology Task Force (2016) reported that use of dual antiplatelet therapy for more than one year after MI reduced the composite risk of cardiovascular death, myocardial infarction, or stroke (hazard ratio: 0.84; 95% CI) but increased significant bleeding (Bittl et al., 2016).

The 2017 European Society of Cardiology focused update on dual antiplatelet therapy in acute coronary syndrome recommended that the use of risk scores may be considered to guide antiplatelet therapy after the percutaneous coronary intervention (Urban et al., 2019). At least six bleeding risk assessment tools are currently available that predict short and long-term bleeding risk in patients taking dual antiplatelet therapy. Among the validated scores, the REACH (2010), Dutch ASA Score (2014), DAPT (2016), PARIS (2016), PRECISE-DAPT (2017), and BLeeMACS (2018) are currently available to predict post PCI bleeding risk.

Although the use of a bleeding scoring tool is highly recommended, the use of a bleeding risk tool has not been adopted by cardiac catheterization laboratory providers within the organization of interest (Norton Healthcare). Implementation of the BLeeMACS instrument into the workflow has the potential to accurately estimate patient-level bleeding risks enabling clinicians to protect patients from unnecessary exposure to potential bleeding. Evaluation of the BLeeMACS tool would allow the clinicians to identify high-risk patients who are potentially deprived of possible therapeutic benefits. It is necessary to extend the concept of using risk scores to prevent short and long-term bleeding and improved clinical outcomes. The use of validated BLeeMACS scores advocates the current guidelines and is an essential step in the right direction for a meaningful clinical practice impact (Baber, 2017).

Problem Statement

Bleeding is recognized as a significant event with a prognostic impact on patients undergoing PCI (Baber, 2017). Thus, there is a need for the use of a bleeding risk assessment tool to identify high bleeding risk in individuals on DAPT who undergo PCI in the cardiac catheterization laboratory. Within the Norton Healthcare Cardiac Catheterization Laboratory, the current workflow involves the use of PCI as a preferred intervention while managing the care

of patients who present with acute coronary syndrome. However, the current workflow does not involve the assessment of bleeding in individuals on DAPT who undergo PCI. Evidence demonstrates that the use of a bleeding risk assessment tool can help identify high bleeding risk patients to tailor the DAPT regime, and duration.

Purpose and Aims

This project aimed to improve the awareness among healthcare providers of the bleeding risk of individuals on DAPT undergoing PCI. The aim was to measure the use of the BLeeMACS risk assessment tool among providers and determine bleeding risk in individuals on DAPT who undergo PCI in the cardiac catheterization laboratory. The tool's use sought to increase the provider's awareness of the BLeeMACS score to identify the patients at an increased risk of bleeding. The project's ultimate goal was to incorporate an evidence-based driven practice change using the BLeeMACS score to identify high-risk patients, as there was no such score for identifying such high-risk patients currently being used in the organization.

Setting and Organizational Assessment

Norton Hospital is an acute care hospital located in the Louisville-Jefferson County metro area with a 1.29 million population with a busy Cardiac Catheterization lab and an established chest pain center. This hospital accepts patients with acute chest pain needing timely PCI within 90 minutes from the first contact to the device, a standard management strategy for reperfusion in STEMI. Norton Healthcare Hospitals in Louisville, Kentucky, are award-winning for Lifeline Gold Plus and Gold awards from the American Heart Association to treat patients who experience myocardial infarction. According to the American Heart Association standards, these are the quality care awards given to organizations that provide cardiac patients quality care. In

the year 2018, Norton Healthcare Hospitals in Louisville provided care to 439 patients with STEMI (Choate, 2019).

Norton Health Care's cardiology department recognizes dual platelet therapy (DAPT) as a cornerstone of management strategy for patients with acute coronary syndrome and had percutaneous intervention (PCI). Individuals are treated in cardiac catheterization by cardiologists, electrophysiologists, physician assistants, and advanced practice nurses.

Ethics /Permissions

The University Institutional Review Board (IRB) and Norton Healthcare Institutional Review Board approval was obtained before starting this quality improvement project. All data collected during the project was kept confidential and was saved under lock all the time. An approval letter was obtained from Chief Nursing Officer/ VP Patient Care Services (See Appendix A) and Quality Management Officer (see Appendix B).

Theoretical Framework

The Kurt Lewin Theory was sought to serve as a theoretical framework for this practice change project (see Appendix C). The Kurt Lewin Change Theory guides a high-level approach to change practice in health care. Kurt Lewin introduced a three-step process that includes unfreezing, simulating a ready-to-change phase, then change simulating the implementation phase, and refreezing simulating, making this change sustain. These three steps are incredibly essential to make a change in practice (Morrison, 2020)

Lewin's theory explains the driving forces that change direction facilitates the desired direction and shift the equilibrium towards that change. This theory also explains the restraining forces that go in the opposite direction, hinder growth, and cause a shift in equilibrium that opposes the change. It also describes stability, which is a state of being stable with no new

change. After the change, the new stability is a steady-state necessary to maintain this new behavior and change (Kritsonis, 2005). There are three steps of Kurt Lewin's theory, which include: Unfreezing, which is a process to leave the old pattern, which could be achieved by increasing the driving forces towards change, and by decreasing the restraining forces. Changing, which is a process of change in thoughts, habits, and behavior to adopt the change, is necessary for the desired change to be productive. Refreezing, which establishes a new habit or behavior that becomes a standard of practice. Refreezing is a crucial stage, as without sticking to the new way, change can go back, and old patterns would be adopted otherwise. Refreezing is a necessary step to maintain a new standard of practice (Morrison, 2020). The Kurt Levin Theory guided step-by-step to enable the implementation and sustain the use of risk assessment tool (BLeeMACS) in practice among patients on dual antiplatelet therapy (DAPT) after a percutaneous coronary intervention (PCI) for Acute Coronary Syndrome (ACS).

Review of Literature

The databases PubMed, CINAHL, Cochrane Library, and Google Scholar were used using search terms; post PCI bleeding, ACS-complications, assessment tools post-PCI, and predicting the risk of bleeding in ACS. The initial search revealed 16,100 publications. Publications were further searched for the English language, in the last 5 years (from 2015 to 2020), in adults, and in the United States which further narrowed down to 411 publications. The publications were narrowed for most current relevant information about the topic and 19 publications were selected for this literature review.

Acute Coronary Syndrome includes STEMI, NSTEMI, and UA. The STEMI and NSTEMI are treated by the percutaneous coronary intervention (PCI) accompanied by guideline-driven dual antiplatelet therapy (Dechant, 2016). When an individual undergoes a PCI, dual

antiplatelet therapy is prescribed to avoid stent thrombosis. Percutaneous Coronary Intervention is associated with risks, including bleeding from the access site, gastrointestinal, and intracranial, epistaxis, bruising, hematoma, and pseudoaneurysm. The radial approach is relatively safer than the femoral approach regarding bleeding from the access site. These patients with bleeding are sometimes readmitted to the hospital most within 30 days of hospital discharge. These patients are at increased risk for subsequent death or MI, especially within the first 60 days after a bleeding-related hospitalization (Valle et al., 2016).

The most significant determinants of post-discharge bleeding are a history of bleeding, peripheral vascular disease, chronic obstructive pulmonary disease, oral anticoagulants, and age of more than 80 years (Ismail et al., 2019). The elderly patients have increased ischemia as well as a bleeding risk due to comorbidity, physical disabilities, complex coronary disease, and frailty. Old age, renal impairment, vascular disease, hypertension, history of previous bleeding, malignancy, and serum hemoglobin are independent factors associated with bleeding risk. The bleeding events include gastrointestinal (GI) bleeding, GI ulcers with bleeding, melena, hematemesis, intracranial bleeding, epistaxis, hemoptysis, hemarthrosis, hematuria, vaginal bleeding in females, retinal bleeding, ecchymosis, and spontaneous bruising (Ismail et al., 2019).

The definition of anemia differed between studies, but baseline anemia was noticed to be one of the strongest independent predictors of bleeding assessed in these risk assessment scores except REACH Registry, in which anemia was not an associated risk factor (Urban et al., 2019). The variables and factors associated with all the six currently available bleeding risk scores have advanced age as the only common variable to all the scores. The other non-modifiable factor associated with higher bleeding risk is the female sex studied in the TRILOGY ACS score. These factors are generally related to other comorbid conditions such as diabetes mellitus,

hypertension, stroke, peripheral neuropathy, h/o previous bleeding, and malignancy. The potentially modifiable factors include anticoagulation, use of non-steroidal anti-inflammatory drugs (NSAIDs) or chronic steroid use, renal function, hemoglobin, and thrombocytopenia. The modifiable factors include the choice of vascular access, the type and duration of DAPT, and invasive management (see Appendix E).

Bleeding Risk Assessment Tools

Among the validated instruments the BRIC-ACS study was completed on 2,520 acute coronary syndrome patients from 2014 to 2016 in patients who underwent PCI in the Chinese population in which 29 nationally recognized tertiary hospitals participated. Post-discharge bleeding's cumulative incidence was 4.9% in patients who completed a one-year follow-up in this study. It was concluded that post-discharge bleeding (PDB) with BARC >2 was associated with a higher risk for a major cardiovascular event (MACE) after a percutaneous intervention (PCI). The constructed BRIC-ACS risk score provides a useful tool for post-discharge bleeding discrimination, particularly among high ischemic and bleeding risk patients (Chen et al., 2019). However, this study was validated in the Chinese population, and many sociocultural factors may have influenced the analysis.

The DAPT instrument was created and meant for patients who have completed 12 months of DAPT without any major ischemic or major bleeding event on dual antiplatelet therapy, not on oral anticoagulation. It considers the variables such as age, history of diabetes mellitus, prior myocardial infarction, hypertension, peripheral vascular disease, cigarette smoking, history of congestive heart failure, and renal insufficiency. The instrument is recommended for guidance in the overall conversation about DAPT and not recommended for or against any medical treatment. The objective of the instrument was to develop a clinical decision

tool to identify patients for harm or benefit from continuing DAPT beyond one year after the percutaneous coronary intervention (Yeh et al., 2016).

External validation of BLeeMACS was done using data from the Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies (SWEDEHEART) registry. The external validation was conducted in 15 hospitals from 10 different countries located in America, Europe, and Asia in population with 96,239 ASC patients who underwent PCI and 93,150 patients without PCI. The BLeeMACS score was internally validated in 4,651 patients randomly selected after dividing the BLeeMACS population into two samples. The older age, renal impairment, vascular disease, hypertension, history of bleeding, malignancy, and serum hemoglobin were variables associated independently with high bleeding risk in BLeeMACS scores (see Appendix F). The incidence rate of bleeding was 3.2 per 100 person-year (95% CI 2.9% to 3.6%) in the BLeeMACS derivation cohort and 3.6 (95% CI 3.1% to 4.2%) in the BLeeMACS internal validation cohort (Raposerias-Roubin et al., 2018). The BLeeMACS instrument is scored and categorized into risk groups were very low risk: 0 – 7 points, low risk: 8 – 16 points, moderate risk: 17 -25 points, and high risk: > 26. The variables age, history of hypertension, history of vascular disease, history of prior bleeding, malignancy, creatinine level, and current hemoglobin are scored individually counted, then added together to a total the overall BLeeMACS score (Raposerias-Roubin et al., 2018).

Strengths of BLeeMACS Score

First, the BLeeMACS score is derived from real-life ACS populations who underwent percutaneous intervention with > 15,000 patients from 15 hospitals across ten different countries of North America, South America, Europe, and Asia. Second, the BLeeMACS score has been

externally validated in a large cohort of more than 90,000 patients, including the entire spectrum of ACS population with and without PCI. Third, the BLeeMACS score is the first instrument that explicitly predicts the risk of post-discharge bleeding in patients with the acute coronary syndrome. Fourth, the BLeeMACS instrument is easy to calculate with seven readily available clinical variables; Fifth, it can be applied as a clinical predictive tool allowing clinicians to tailor the appropriate antithrombotic treatment according to the individual risk of bleeding. Sixth, the BLeeMACS bleeding score was externally validated in a large ACS population treated with new p2y12 inhibitors, commonly used today (Raposerias-Roubin et al., 2018).

The availability of the validated BLeeMACS instrument can help clinicians decide individualized antithrombotic therapy as a strategic plan for the ACS population. The BLeeMACS score allows identifying the patients at higher risk for bleeding to entail management.

Intervention

The project's intervention was based on the Plan-Do-Study-Act (PDSA) design and was conducted in stages (see Appendix D). The Clinical manager of the cardiac catheterization laboratory was notified using institutional email 2 weeks before the start of the project and a reminder email was sent 1 week before the start of the project. A total of 19 Cardiologists working in cardiac catheterization laboratory of Norton Healthcare attended the education session. A pre-education assessment was completed using a pre-survey form using a Likert scale to assess the provider's understanding of the risk assessment tool in June 2021 immediately before the education session (Appendix G). A 20-minute education session of the BLeeMACS instrument was provided to providers during the mandatory clinical monthly meeting in June 2021, which consisted of a PowerPoint presentation. Post-education assessment was completed

immediately after PowerPoint presentation using the post-survey form (Appendix H). The intervention intended to measure provider awareness and comfort of using BLeeMACS instrument.

Participants

Inclusion criteria: The participants in this project were cardiology providers, MDs, APRNs, and PAs working in the cardiac Catheterization Laboratory. A verbal consent to participate was obtained from participants during the in-service before starting the project in the third week of May 2021.

Exclusion criteria: The cardiology providers not working in the Cardiac Catheterization Laboratory.

Data Collection

All data collected was coded using a codebook. The security of data was not compromised at any level during this project conduction. The data collection included the demographics of the health care provider such as title, gender, and years of experience as well as participants' answers to the pre-and post-education survey questionnaires (see Appendices G & H). The DNP student collaborated with the Clinical Manager of the Cardiac Catheterization Laboratory, to collect pre-and post-survey forms before and after the education session respectively.

The data were used to identify Low Bleeding Risk (LBR), and High Bleeding Risk (HBR) by modification of the BLeeMACS instrument, merging very low risk (score 0-7) and low risk (score 8-16) as Low Bleeding Risk, and moderate risk (scores 17-25) combined with high risk (scores more than 26) as High Bleeding Risk.

Measurements

Demographics

Demographic data were collected as a component of the pre- and post-surveys. Demographics included title of health care provider (MD, advanced practice nurse or physician assistant), as well as years of experience. The participants were asked to select by check mark which title, and years of experience best represented them. Years of experience was divided into four options: > 15 years, 10-15 years, 5-10 years, 2-5 years, and < 2 years. One pre- and one post-survey form was collected from each participant before and after the education session respectively, and these forms were marked from 1-19 and it was made sure to present same form number to a specific participant.

Awareness

Awareness of bleeding risk using pre-and post-survey questionnaires was developed by the DNP student (Appendix G, Appendix H). A Likert 1-5 scale was used to score the participant's level of agreement with one out of five scoring options; from strongly disagree (1), disagree (2), not sure (3), agree (4), and strongly agree (5). The maximum score of 45 corresponds with strongly agree to 9 questions on the survey. Each form presented was numbered from 1-19, and one such numbered pre and one post-survey form was presented before and after education respectively to each participant for response.

BLeeMACS Instrument

The providers were asked to complete a BLeeMACS instrument for each patient assessed during the project implementation. BLeeMACS is externally and internally validated risk assessment tool which is used to identify high bleeding risk patients undergoing PCI. The older

age, renal impairment, vascular disease, hypertension, h/o bleeding, malignancy, and serum hemoglobin are variable used while scoring the BLeeMACS instrument (Appendix F).

Bleeding Risk Groups

Bleeding risk was identified as low-risk and high-risk bleeding using the BLeeMACS score. The BLeeMACS risk groups were categorized as low-risk when scores were $\leq$ 16 and high-risk when scores were $\geq$ 17.

Evaluation

Descriptive statistics were used to analyze demographic data and to determine the proportion of individuals with low-risk bleeding and individuals with high-risk bleeding classifications. Inferential statistics were used to evaluate the intervention. Statistical analysis was performed using IBM SPSS (Version 27). A *p*-value of < 0.05 was used to determine statistical significance. The paired t-test was used to compare mean scores on the pre-and post-test survey results to evaluate the provider's awareness of the BLeeMACS risk assessment tool. The paired t-test was used because one pre-survey and one post-survey form was presented and collected from same participant before and after education session and these forms were numbered from 1 to 19.

Results

Demographics

There were 19 participants in the quality improvement project. Of these, 100% reported the title of MD. There were 42.1% of participants who had more than 15 years' experience; 31.6% had 10-15 years' experience; 15.8 % had 5-10 years of experience; 5.3% had 2-5 years of experience, and 5.3% had less than 2 years of experience.

Awareness

A paired sample *t*-test was used to analyze data on the mean differences of responses on the pre-survey and the post-survey after all the assumptions of the paired *t*-test were met. Table 1 demonstrates the mean differences for each of the survey questions.

Five of the nine survey questions demonstrated a statistically significant difference. The question "A risk assessment tool is needed/helpful to identify patient at risk for bleeding" demonstrated a pre-survey mean score as 4.63 $\pm$ 0.49, and post-survey mean score was 4.94 $\pm$ 0.22 ($p = 0.01$) revealing a statistically significant difference. The question "Do you feel a risk assessment tool will help easy flow in the unit to identify at-risk patients?" demonstrated a pre-survey mean scores as 4.57 $\pm$ 0.60, and post-survey mean score as 4.89 $\pm$ 0.31 ($p = 0.03$) revealing a statistically significant difference. The question "Risk assessment tool should be effectively used in practice" demonstrated a pre-survey mean scores as 4.73 $\pm$ 0.45, and post-survey mean score as 4.94 $\pm$ 0.22 ($p = 0.04$) thus revealing a statistically significant difference. The question "Do you want the documentation tab in EPIC to quickly identify high-risk patients using score/scale?" demonstrated, a pre-survey mean scores as 4.63 $\pm$ 0.49, and post-survey mean score as 4.84 $\pm$ 0.37 ($p = 0.04$) revealing a statistically significant difference. In question, "Are you open to change practice (will use risk assessment tool)?" demonstrated a pre-survey mean scores as 4.52 $\pm$ 0.61, and post-survey mean score as 4.78 $\pm$ 0.41 ($p = 0.05$) which demonstrated a statistically significant difference. The remainder of mean differences for each question did not demonstrate any significant statistical difference.

Bleeding Risk Group

There were 40 out of total 108 (37%) who were identified to be low-risk and 68 out of total 108 (63%) identified as high-risk using the predetermined BLeeMACS scoring.

Discussion

ACC/AHA recommends dual antiplatelet therapy for at least one year for patients receiving drug-eluting stents after coronary artery syndrome treated with percutaneous coronary intervention (Bashore et al., 2019). Bleeding being unavoidable complication of antithrombotic agents, is recognized as a significant event with a prognostic impact in patients undergoing PCI approximating the coronary thrombosis (Baber, 2017). Major bleeding is associated with threefold increased risk of mortality in the first year of acute coronary artery event thus leading to adverse outcomes (Ismail et al., 2019). Therefore, there is a need for the use of a bleeding risk assessment tool to identify high bleeding risk in individuals on DAPT who undergo PCI in the cardiac catheterization Laboratory. Within the Norton Healthcare Cardiac Catheterization Laboratory, the current workflow involves the use of PCI as a preferred intervention while managing the care of patients who present with acute coronary syndrome. However, the current workflow does not involve the assessment of bleeding in individuals on DAPT who undergo PCI. Evidence demonstrates that the use of a bleeding risk assessment tool can help identify high bleeding risk patients to tailor the DAPT regime, and duration.

This quality improvement project sought to improve the awareness among healthcare providers of the bleeding risk of individuals on dual antiplatelet therapy undergoing percutaneous coronary intervention. It was also sought to implement the risk assessment tool to identify high bleeding risk patients using BLeeMACS.

The findings from the results of the quality improvement project shows the evidence of improvement in the awareness of need, importance, and significance of identifying high bleeding risk patients. Therefore, it is evident that education of cardiology health care providers does

improve the awareness of bleeding risk assessment tool. The use of instrument would help them identify and categorize the patient at risk for bleeding who undergo PCI and are on DAPT.

Identification of high bleeding risk patients was determined using the BLeeMACS tool which provided an opportunity for tailored interventions. Patients with high risk of bleeding remain at an increased risk of both bleeding events, as well as ischemic events after percutaneous coronary intervention (Sorrentino et al., 2020). Thus, the use of the BLeeMACS instrument is critical in the assessment of bleeding risk to offer targeted interventions.

Practice Implications

The bleeding after percutaneous intervention in patients with acute coronary syndrome on dual antiplatelet therapy is an important clinical event. There was need to adopt strategies focused on minimizing the risk of bleeding in clinical practice. The evidence supported the use of a validated risk assessment tool. The BLeeMACS score which was explored as validated instrument was used to assist clinicians to identify high-risk bleeding in patients on DAPT undergoing PCI.

This quality improvement project assessed the provider's awareness of the BLeeMACS instrument to identify the patients at an increased risk of bleeding. Findings from this project were shared to inform the organization’s decision to incorporate the BLeeMACS score into the electronic health EPIC system for the cardiology healthcare providers to quickly assess patients for high risk of bleeding. Moreover, it would be there for the continued assessment of all such patients who present with acute coronary syndrome needing percutaneous intervention to ensure this project's sustainability. This project was aimed to improve the awareness among healthcare providers of the bleeding risk of individuals on DAPT undergoing PCI. The aim was to measure the use of the BLeeMACS risk assessment tool among providers and determine bleeding risk in

individuals on DAPT who undergo PCI in the cardiac catheterization laboratory. The project's goal was to support an evidence-based practice change by using the BLeeMACS score to identify high-risk patients as there was no such score for identifying such high-risk patients currently being used in the organization. The project's feasibility could be reflected by the need for such a score in the catheterization laboratory to quickly identify high-risk patients. The sustainability could be reflected by the availability of this scale in the electronic health record EPIC system for documentation for identification of high-risk bleeding in patients on dual antiplatelet therapy (see Appendix E)

Dissemination

Findings from this quality improvement project supported disseminating an oral presentation to Norton's leadership team, cardiac catheterization laboratory providers, and the University of Louisville School of Nursing. Dissemination also includes submitting a poster to the American Nursing Association Seminar and manuscript submission to the Journal of American Association of Nurse Practitioners (JAANP) for publication. The abstract would be submitted to American Heart Association for presentation at the annual scientific meeting.

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Table 1

Pre- and Post- Survey Questionnaire Results

Survey question	Pre-survey mean score	Post-survey mean score	p-value
1. Do you feel Bleeding in patients on DAPT after PCI is a significant problem?	4.68 ± 0.74	4.84 ± 0.68	0.083
2. A risk assessment tool is needed / helpful to identify patients at risk for bleeding.	4.63 ± 0.49	4.94 ± 0.22	0.010
3. Risk assessment tool should be User-friendly/comfortable to work with	4.89 ± 0.31	5.00 ± 0.00	0.163
4. Do you feel a risk assessment tool will help easy flow in the unit to identify at-risk patients?	4.57 ± 0.60	4.89 ± 0.31	0.030
5. Identifying variables/Factors affecting bleeding in such a patient is important.	4.78 ± 0.41	4.94 ± 0.22	0.083
6. Education on risk assessment tool will help implement a risk assessment tool in practice.	4.68 ± 0.67	4.84 ± 0.50	0.083
7. Risk assessment tool should be effectively used in practice.	4.73 ± 0.45	4.94 ± 0.22	0.042
8. Do you want the documentation tab in EPIC to quickly identify high-risk patients using score/scale?	4.63 ± 0.49	4.84 ± 0.37	0.042
9. Are you open to change the practice (will use risk assessment tool)?	4.52 ± 0.61	4.78 ± 0.41	0.056

Note. Pre-education survey questionnaire and post education survey questionnaire (on awareness and understanding of BLeeMACS, a bleeding risk assessment tool) results table showing mean scores and p-values.

Appendix A (Letter of Recommendation)

NORTON HOSPITAL

P.O. Box 35070
Louisville, KY 40232-5070
(502) 629-8000

January 20, 2021

To whom is may concern;

Ghulam Mustafa Mughal is currently an employee at Norton Hospital and completing his DNP program through University of Louisville. His project *titled Implementation of a Risk Assessment Tool in the Cardiac Catheterization Laboratory to Identify High Bleeding Risk Patients on DAPT after PCI* has been reviewed by myself. I support and approve implementation of this project at Norton Hospital after appropriate Institutional Review Board approvals. If further information is needed please contact me directly.

Kim Flanders

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VP Patient Care Services/Chief Nursing Officer
Norton Hospital
Kimberly.flanders@nortonhealthcare.org
200 E Chestnut St.
Louisville, KY 40202
Office -502-629-8032
Cell- 309-339-2902

Appendix B (Letter of Recommendation)

NORTON HOSPITAL

P.O. Box 35070
Louisville, KY 40232-5070
(502) 629-8000

From the Desk of Lisa Sullivan, Medical Staff Services/Quality Management

January 20, 2021

Subject: Ghulam Mustafa Mughal – Post PCI Bleeding Project

To Whom It May Concern;

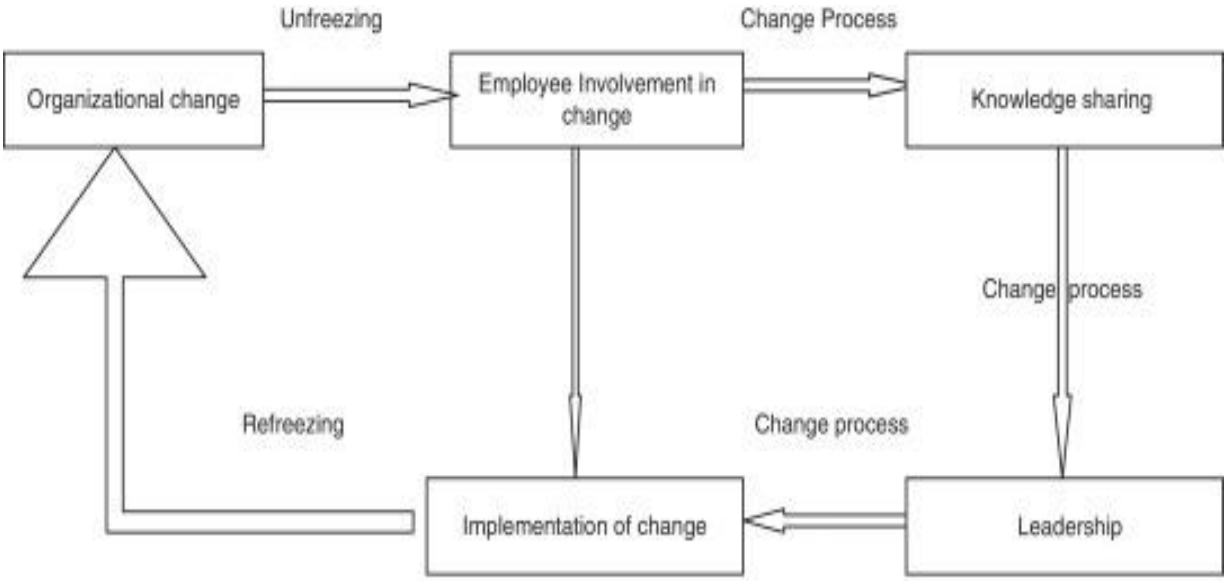
Please be advised that Ghulam Mustafa Mughal, University of Louisville School of Nursing DNP Acute Care Student, is approved to conduct a Post PCI Bleeding Project in the Cardiac Catheterization Laboratory of Norton Hospital Downtown. The quality improvement project will encompass the Implementation of a Risk Assessment Tool in the Cardiac Catheterization Laboratory to Identify High Bleeding Risk Patients on DAPT after PCI.

If you should have questions, please call me, 502-629-3193.

Sincerely,

Lisa Sullivan
/ls

Appendix C (Kurt Lewis change Theory Model)



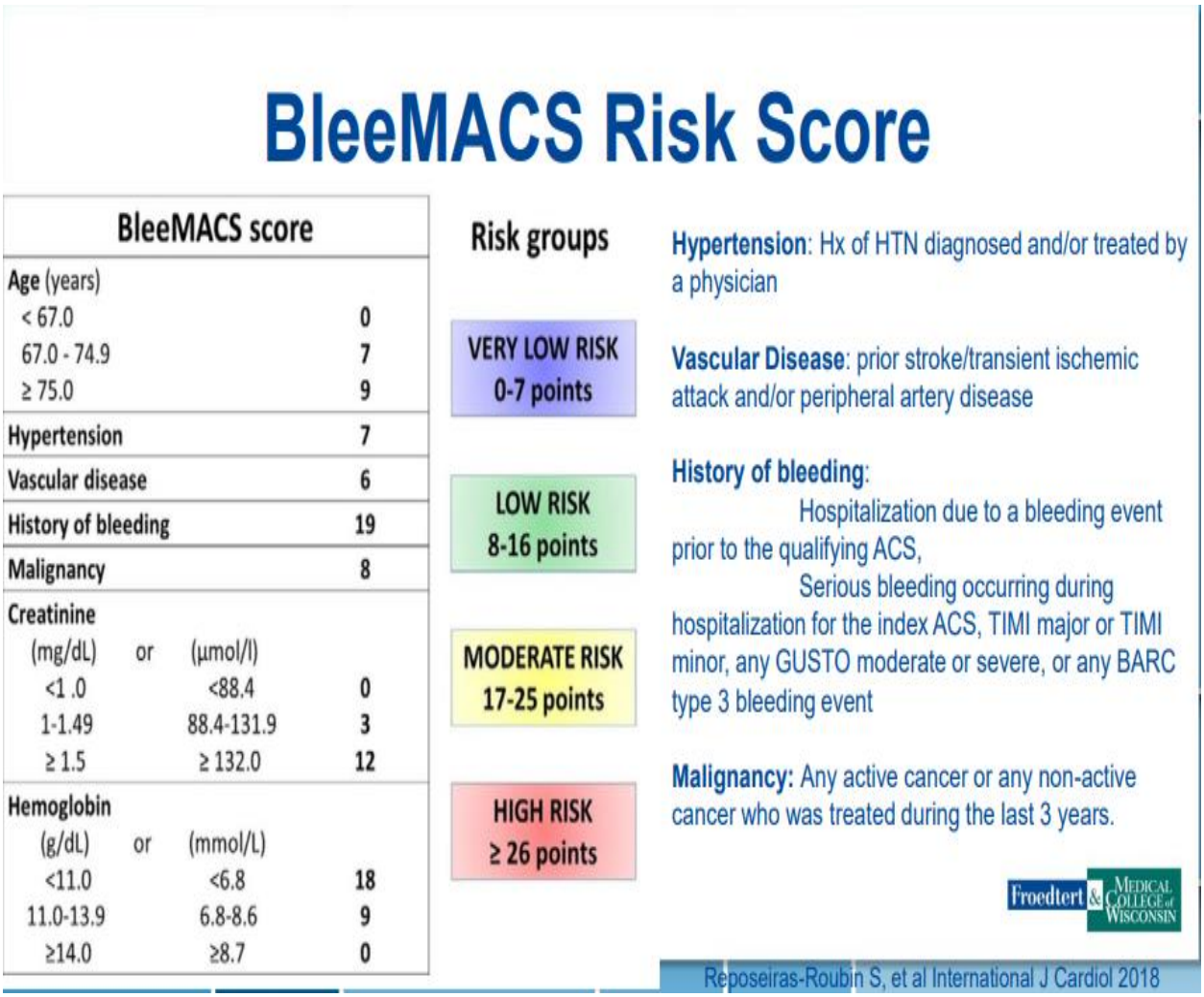
Organizational change process showing different stages

Appendix D (Do Study Act Plan) Design

Appendix E (Bleeding Risk Scores Table)

	PARIS	DAPT	PRECISE-DAPT	TRILOGY ACS	BLeeMACS
Clinical context	DAPT after PCI TT included	DAPT after PCI After 12 months, events free	DAPT after PCI TT not included	DAPT without revascularization	DAPT after PCI TT included.
Variables	Age BMI Current smoking Anemia Renal dysfunction TT at discharge	Age Current smoking DM MI at presentation Prior PCI or Prior MI Paclitaxel eluting stent diameter < 3 mm CHF or LVEF < 30%	Age White blood cells Hemoglobin Creatinine clearance Prior bleeding	Age Gender Angiography performed before randomization Creatinine Hemoglobin	Age Hypertension Vascular disease Prior bleeding Malignancy Creatinine Hemoglobin
Classification	Low risk: 0–2 Intermediate risk: 4–7 High risk: ≥ 8	Score ≥ 2: long DAPT (30 months) Score < 2: standard DAPT (12 months)	Score ≥ 25: short DAPT (3–6 months) Score < 25: standard/long DAPT (12–24 months)		Very low risk: ≤ 7 Low risk: 8–16 Moderate risk: 17–25 High risk: ≥ 26
Prediction	From discharge to 24 months	From 12 months to 36 months	From discharge to 24 months	From discharge to 14 months	From discharge to 12 months

Appendix F (BLeeMACS Risk Score)



Appendix G (Pre-Test Survey)

Pre-test Survey questions 1 (Strongly Disagree) to 5 (Strongly Agree)

1. **Do you feel Bleeding in patients on DAPT after PCI is a significant problem?**

   1 2 3 4 5

2. **A risk assessment tool is needed / helpful to identify patients at risk for bleeding.**

   1 2 3 4 5

3. **Risk assessment tool should be User-friendly/comfortable to work with**

   1 2 3 4 5

4. **Do you feel a risk assessment tool will help easy flow in the unit to identify at-risk patients?**

   1 2 3 4 5

5. **Identifying variables/Factors affecting bleeding in such a patient is important.**

   1 2 3 4 5

6. **Education on risk assessment tool will help implement a risk assessment tool in practice.**

   1 2 3 4 5

7. **Risk assessment tool should be effectively used in practice.**

   1 2 3 4 5

8. **Do you want the documentation tab in EPIC to quickly identify high-risk patients using score/scale?**

   1 2 3 4 5

9. **Are you open to change the practice (will use risk assessment tool)?**

   1 2 3 4 5

10. **What are your years of experience?**

    >15years 10-15 years 5-10 years 2-5 years < 2 years

11. **What is your title?**

    MD APRN PA

Appendix H (Post- test Survey)

Post-test Survey questions 1 (Strongly Disagree) to 5 (Strongly Agree)

1. **Do you feel Bleeding in patients on DAPT after PCI is a significant problem?**

   1 2 3 4 5

2. **A risk assessment tool is needed / helpful to identify patients at risk for bleeding.**

   1 2 3 4 5

3. **Risk assessment tool should be User-friendly/comfortable to work with**

   1 2 3 4 5

4. **Do you feel a risk assessment tool will help easy flow in the unit to identify at-risk patients?**

   1 2 3 4 5

5. **Identifying variables/Factors affecting bleeding in such a patient is important.**

   1 2 3 4 5

6. **Education on risk assessment tool will help implement a risk assessment tool in practice.**

   1 2 3 4 5

7. **Risk assessment tool should be effectively used in practice.**

   1 2 3 4 5

8. **Do you want the documentation tab in EPIC to quickly identify high-risk patients using score/scale?**

   1 2 3 4 5

9. **Are you open to change the practice (will use risk assessment tool)?**

   1 2 3 4 5

10. **What are your years of experience?**

    >15years 10-15 years 5-10 years 2-5 years < 2 years

11. **What is your title?**

    MD APRN PA