



Reduce the Risk: PCI Bleed

A Campaign of the
American College of Cardiology



Reduce the Risk: PCI Bleed

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ACC Reduce the Risk: PCI Bleed Campaign: A New Tool “Insight on implementing the 2020 ACC Expert Consensus Decision Pathway for Management of Bleeding”

May 5, 2021 12-1pm ET

Webinar #9



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Agenda

- Campaign Updates
- Introduction of the New Campaign Tool
- Q& A
- Announcements



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Campaign Celebrations!

- Enrollment completed with 206 participants
- Final Campaign Data Submission completed
- Assessment, Toolkit and Webinars will remain available to all registry participants
- New Tool added to the Campaign Toolkit



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Reduce the Risk: PCI Bleed Toolkit



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 - Assessment
 - Toolkit
 - Webinars
 - Reduce the Risk Listserv
- Reduce the Risk - PCI Bleed Participation Certificate

Reduce the Risk: PCI Bleed

Anticipate. Prepare. Save Lives.

The ACC's **Reduce the Risk: PCI Bleed** Quality Campaign is focused on minimizing PCI-associated bleeding risks and saving patient lives through widespread adoption of evidence-based best practices.

Building on the ACC's proven track record in helping hospitals and cardiovascular professionals take advantage of key strategies to close gaps in guideline-recommended care, **Reduce the Risk: PCI Bleed** leverages the power of the **CathPCI Registry®** to help hospitals and clinicians



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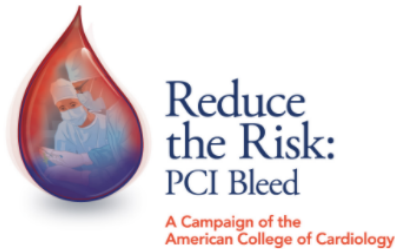
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Reduce the Risk: PCI Bleed Toolkit



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Assessment

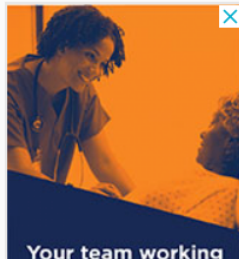
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Reduce the Risk: PCI Bleed Toolkit

The ACC has curated evidence-based tools to help you decrease PCI bleeding at your facility. Click on each section to find targeted tools for each Campaign metric:

Metric 1: in-hospital risk-standardized rate of bleeding events for all PCI patients.

Metric 2: Proportion of PCI procedures with transfusion of whole blood or red blood cells.

Metric 3: Procedures with an observed bleeding event.

Metric 4: Anticoagulation utilization.

Metric 5: Access site utilization.

Metric 6: Method for closure for arterial access site.

➤ Preprocedural (Tools to address Metrics #1,3,4,5, and 6)

➤ Intraprocedural (Tools to address Metrics #1, 5, and 6)

➤ Postprocedural (Tools to address Metrics #1, 3, 5, and 6)

➤ Pharmacotherapy (Tools to address Metrics #1, 2, 3, 4, 5, 6)

➤ EHR Integration (Tools to address Metrics #1, 4, 5, and 6)

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➤ Preprocedural (Tools to address Metrics #1,3,4,5, and 6)

➤ Intraprocedural (Tools to address Metrics #1, 5, and 6)

➤ Postprocedural (Tools to address Metrics #1, 3, 5, and 6)

▼ Pharmacotherapy (Tools to address Metrics #1, 2, 3, 4, 5, 6)

Metric	Tools
Metric 1: in-hospital risk-standardized rate of bleeding events for all PCI patients Metric 4: Anticoagulation utilization	General Considerations for Anticoagulation and Antiplatelet Therapy in PCI
Metric 1: in-hospital risk-standardized rate of bleeding events for all PCI patients Metric 4: Anticoagulation utilization	Expert Consensus Decision Pathway for Periprocedural Management of Anticoagulation in Patients With NVAF
Metric 1: in-hospital risk-standardized rate of bleeding events for all PCI patients Metric 4: Anticoagulation utilization Metric 2: Proportion of PCI procedures with transfusion of whole blood or red blood cells	2020 ACC Expert Consensus Decision Pathway for Anticoagulant and Antiplatelet Therapy in Patients With Atrial Fibrillation or Venous Thromboembolism Undergoin 2020 Expert Consensus Decision Pathway on Management of Bleeding in Patients on Oral Anticoagulants



EXPERT CONSENSUS DECISION PATHWAY

2020 ACC Expert Consensus Decision Pathway on Management of Bleeding in Patients on Oral Anticoagulants

A Report of the American College of Cardiology Solution Set Oversight Committee

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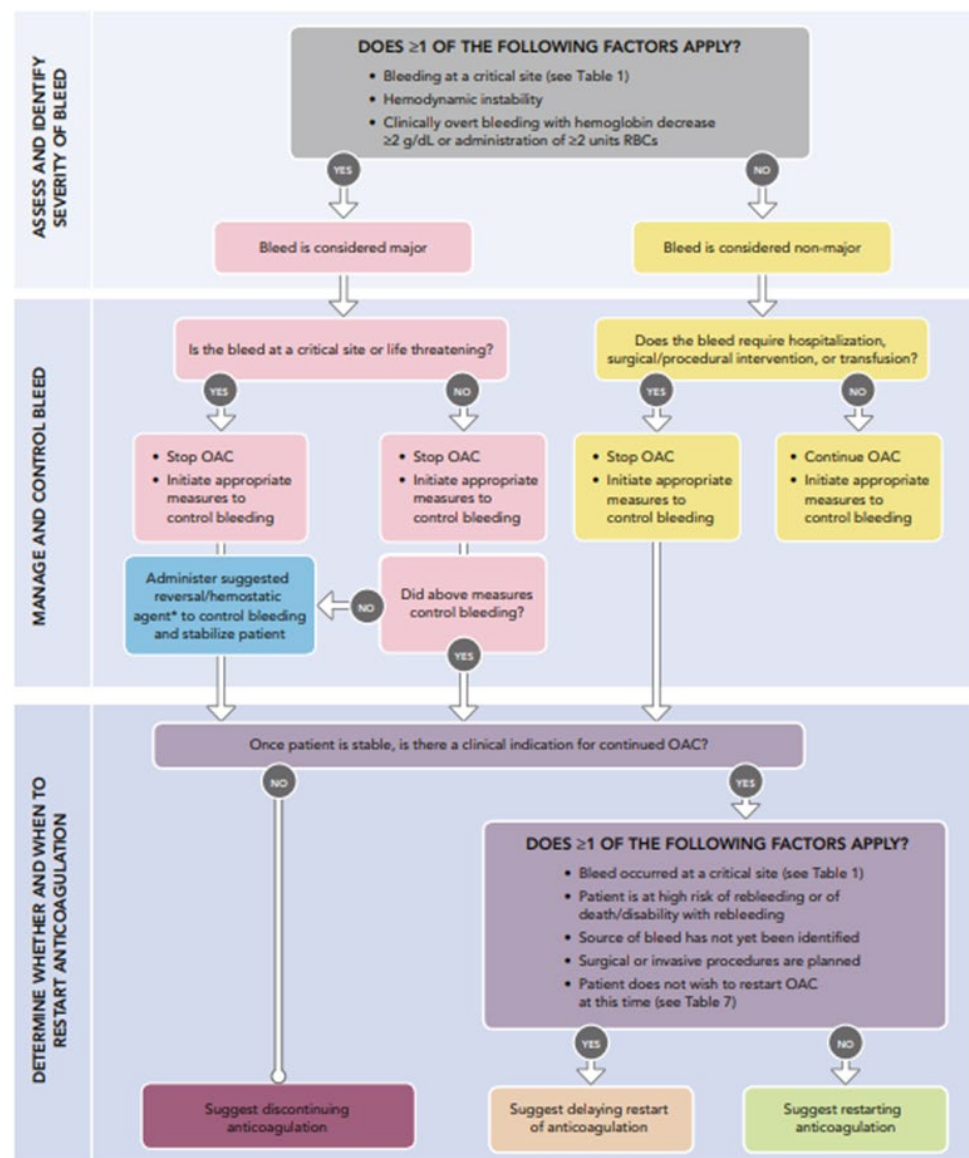
Medical Director

*Center for Cardiovascular Analytics, Research, and Data
Science (CARDS)
Providence Health Institute*



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FIGURE 1 Summary Graphic

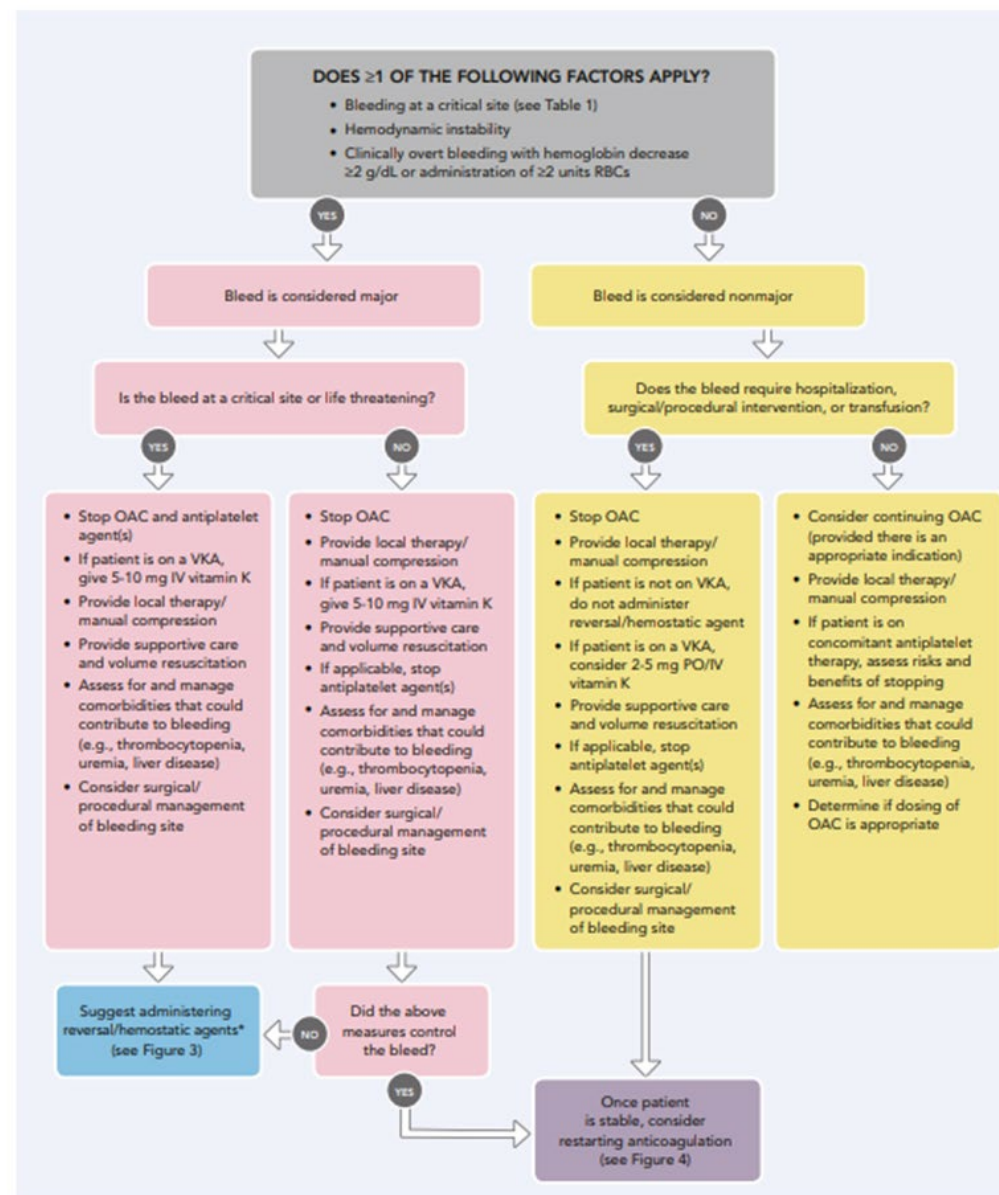


DOAC = direct-acting oral anticoagulant; OAC = oral anticoagulant, including DOACs and VKAs; PCC = prothrombin complex concentrate; RBC = red blood cell; VKA = vitamin K antagonist *Reversal/hemostatic agents include repletion strategies such as PCCs, plasma, vitamin K, and specific reversal agents for DOACs (e.g., idarucizumab for dabigatran; andexanet alfa for apixaban or rivaroxaban).



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FIGURE 2 Assessing Bleed Severity and Managing Major and Non-Major Bleeds

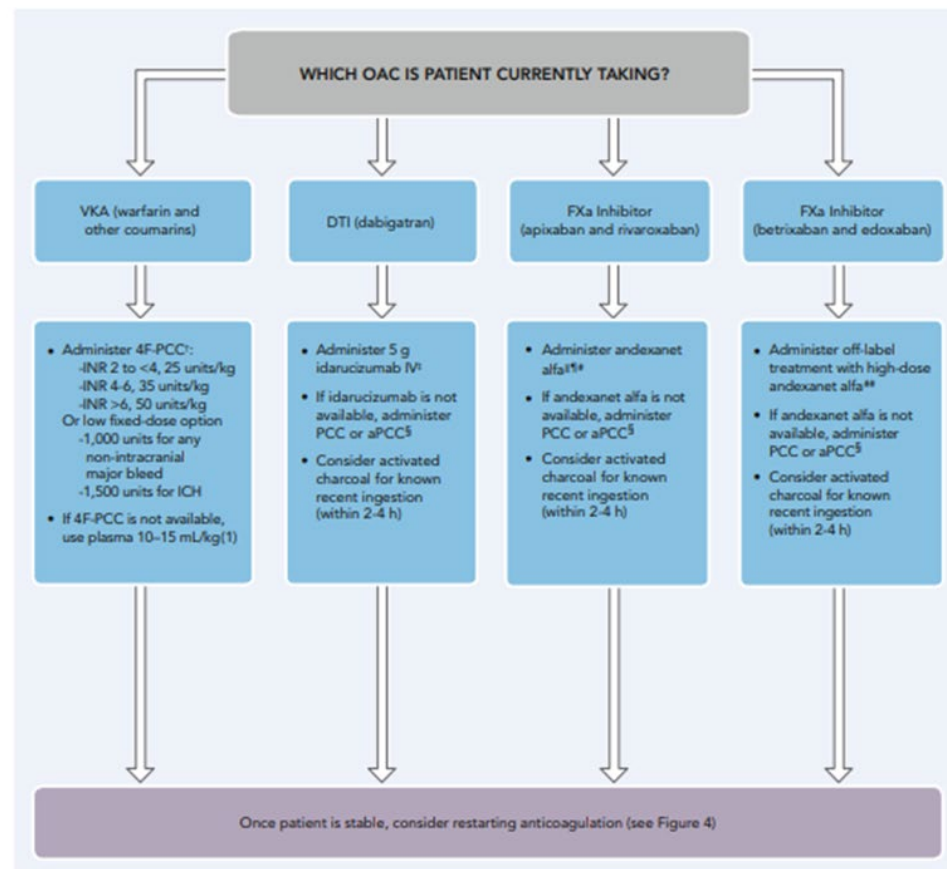


DOAC = direct-acting oral anticoagulant; IV = intravenous; OAC = oral anticoagulant, including DOACs and VKAs; PCC = prothrombin complex concentrate; PO = per os "by mouth"; RBCs = red blood cells; VKA = vitamin K antagonist *Reversal/hemostatic agents include repletion strategies such as PCCs, plasma, vitamin K, and specific reversal agents for DOACs (e.g., idarucizumab for dabigatran; andexanet alfa for apixaban or rivaroxaban).



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FIGURE 3 Considerations for Reversal/Hemostatic Agents*



4F-PCC = four-factor prothrombin complex concentrate; aPCC = activated prothrombin complex concentrate; DOAC = direct-acting oral anticoagulant; DTI = direct thrombin inhibitor; FXa = Factor Xa; h = hours; ICH = intracranial hemorrhage; INR = international normalized ratio; IV = intravenous; OAC = oral anticoagulant, including DOACs and VKAs; PCC = prothrombin complex concentrate; VKA = vitamin K antagonist.

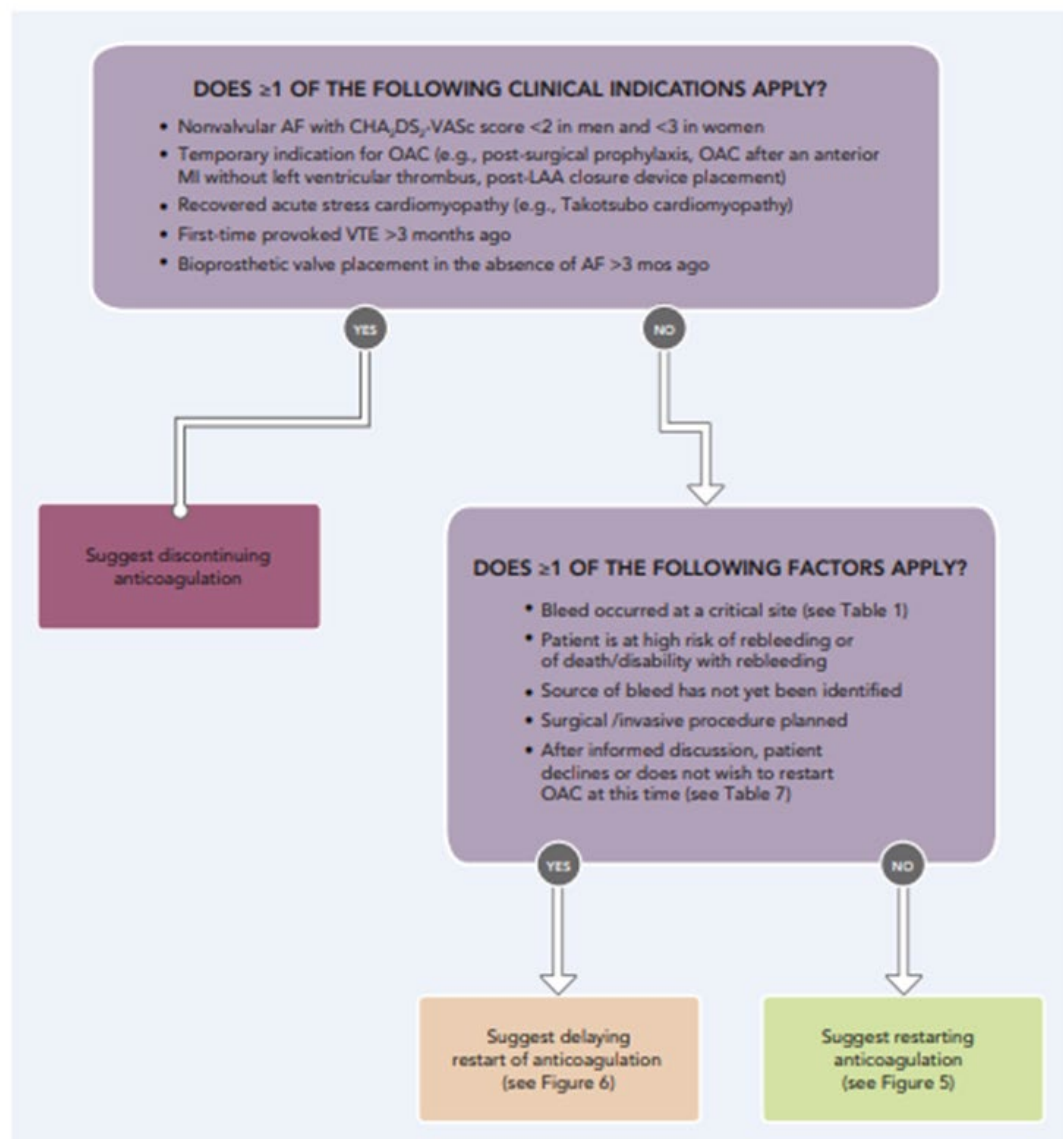
*Reversal/hemostatic agents include repletion strategies such as PCCs, plasma, vitamin K, and specific reversal agents for DOACs (e.g., idarucizumab for dabigatran; andexanet alfa for apixaban or rivaroxaban). ¹When PCCs are used to reverse VKAs, vitamin K should also always be given (see Figure 2 for dosing guidance). ⁴If bleeding persists after reversal and there is laboratory evidence of a persistent dabigatran effect, or if there is concern for a persistent anticoagulant effect before a second invasive procedure, a second dose of idarucizumab may be reasonable. ⁵Refer to prescribing information for maximum units. ⁶In patients taking ≤ 5 mg apixaban or ≤ 10 mg rivaroxaban, administer low dose andexanet alfa = initial IV bolus 400 mg at a target rate of 30 mg/min, followed by IV infusion 4 mg/min for up to 120 minutes. ⁷In patients taking >5 mg apixaban or >10 mg rivaroxaban, administer high dose andexanet alfa = initial IV Bolus 800 mg at a target rate of 30 mg/min, followed by IV infusion 8 mg/min for up to 120 minutes. ⁸ANEXA-4 full report excluded patients with DOAC levels <75 ng/ml because those patients were considered to have clinically insufficient levels for reversal agent. If drug effect/level can be assessed without compromising urgent clinical care decisions, then assessment should be performed before andexanet alfa is administered ⁹In patients taking betrixaban or edoxaban, administer high dose andexanet alfa = initial IV Bolus 800 mg at a target rate of 30 mg/min, followed by IV infusion 8 mg/min for up to 120 minutes.

1. Sarode R, Milling TJ Jr, Refaai MA, et al. Efficacy and safety of a 4-factor prothrombin complex concentrate in patients on vitamin K antagonists presenting with major bleeding: a randomized, plasma controlled, phase IIIb study. *Circulation* 2013; 128:1234-43.



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FIGURE 4 Considerations for Restarting Anticoagulation



AF = atrial fibrillation; CHA₂DS₂-VASc = Congestive heart failure, Hypertension, Age (>65 = 1 point, ≥75 = 2 points), Diabetes, previous Stroke/transient ischemic attack (2 points); LAA = left atrial appendage; MI = myocardial infarction; mos = months; OAC = oral anticoagulant, including VKAs and DOACs; VKA = vitamin K antagonist; VTE = venous thromboembolism.



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2020 ACC Expert Consensus Decision Pathway for Anticoagulant and Antiplatelet Therapy in Patients With Atrial Fibrillation or Venous Thromboembolism Undergoing Percutaneous Coronary Intervention or With Atherosclerotic Cardiovascular Disease



A Report of the American College of Cardiology Solution Set Oversight Committee

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FIGURE 2 Patient With AF on OAC Who Now Needs PCI: Post-Procedure and Long-Term Management of Antithrombotic Therapy

Medication Key

Antiplatelet therapy

APT = Antiplatelet therapy

ASA = Aspirin

$P2Y_{12}^i$ = $P2Y_{12}$ inhibitor

Anticoagulant therapy

OAC = Oral anticoagulant

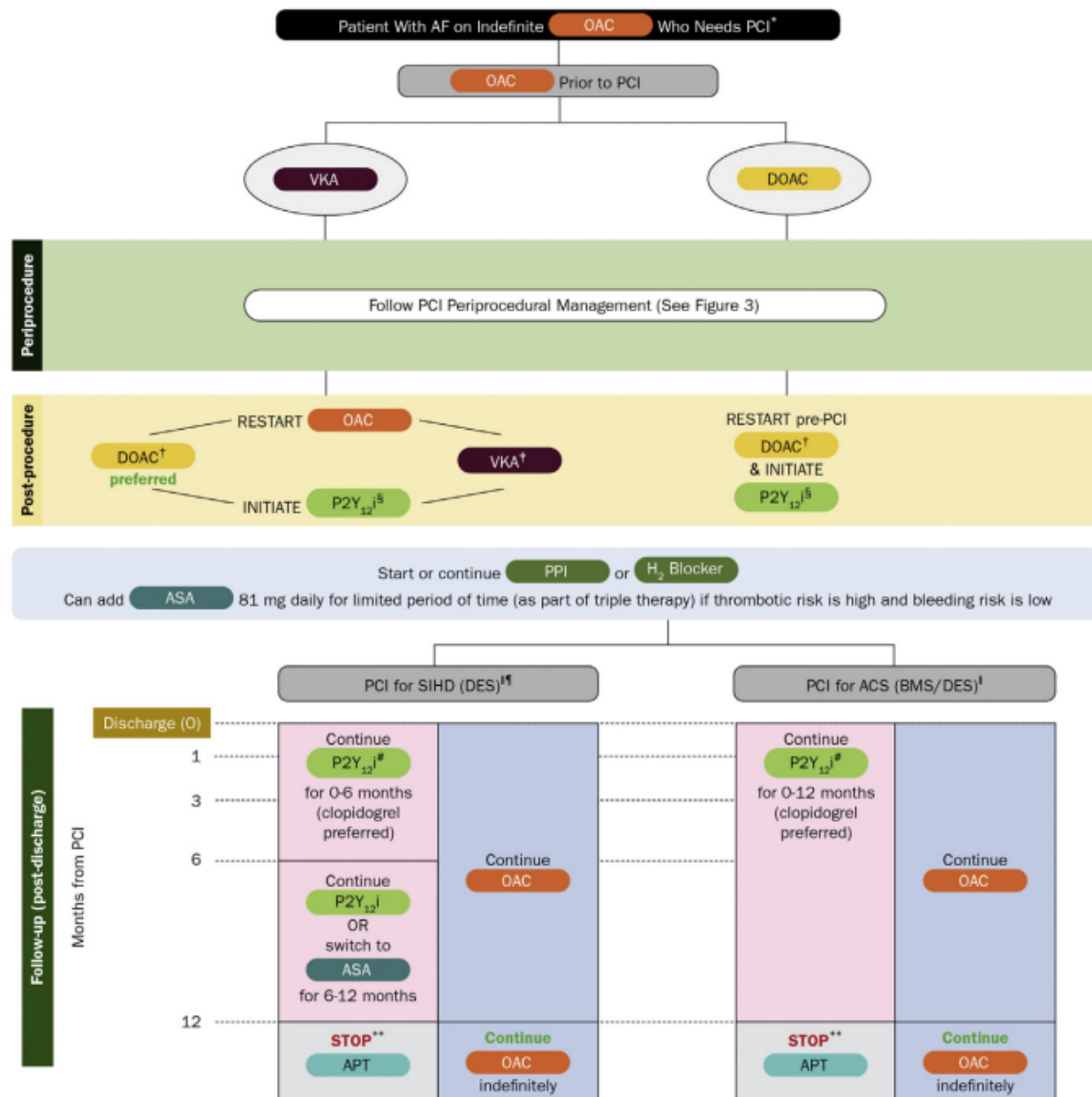
DOAC = Direct oral anticoagulant

VKA = Vitamin K antagonist

Acid Blockers

H₂ Blocker = Histamine H₂-receptor antagonist

PPI = Proton pump inhibitor



* See Table 2: Dosing Table for Atrial Fibrillation.

† See text for DOAC dosing.

† For those on a VKA, aspirin (81 mg daily) should be continued until the INR is in the therapeutic range.

§ Clopidogrel preferred over prasugrel/ticagrelor to the extent possible.

II If BMS, duration of P2Y12i is 1 month.

¶ The time frames listed here represent treatment durations post-PCI.

Early discontinuation in those at high risk of bleeding is reasonable (after 3 months for SIHD and after 6 months for ACS).

****** If perceived thrombotic risk is high and bleeding risk is low, continuation of SAPT (ASA 81 mg daily or clopidogrel 75 mg daily) beyond 12 months is reasonable.

AC = anticoagulant; ACS = acute coronary syndrome; AF = atrial fibrillation; BMS = bare metal stent; DES = drug-eluting stent; INR = international normalized ratio; PCI = percutaneous coronary intervention; SIHD = stable ischemic heart disease.

FIGURE 3 Patient on AC Who Now Needs PCI: Periprocedural Management of Antithrombotic Therapy

Medication Key

Antiplatelet therapy

ASA = Aspirin

P2Y₁₂ⁱ = P2Y₁₂ inhibitor

Anticoagulant therapy

DOAC = Direct oral anticoagulant

LMWH = Low-molecular-weight heparin

VKA = Vitamin K antagonist

Acid Blockers

H₂ Blocker = Histamine H₂-receptor antagonist

PPI = Proton pump inhibitor

Elective: Procedure can be performed on an outpatient basis or during a subsequent hospitalization without significant risk of infarction or death. For stable inpatients, the procedure is performed during hospitalization for convenience, NOT because it is urgent or emergent.

Urgent: Procedure should be performed on an inpatient basis prior to discharge due to significant risk of ischemia, infarction, and/or death.

Emergent: Procedure should be performed as soon as possible due to substantial concerns that ongoing ischemia and/or infarction could lead to death. "As soon as possible" refers to a patient of sufficient acuity to warrant cancelling a scheduled case to perform procedure immediately in the next available room during business hours, or to activate the on-call team during off-hours.

* Some catheterization labs may use a lower threshold (e.g., ≤ 1.5).

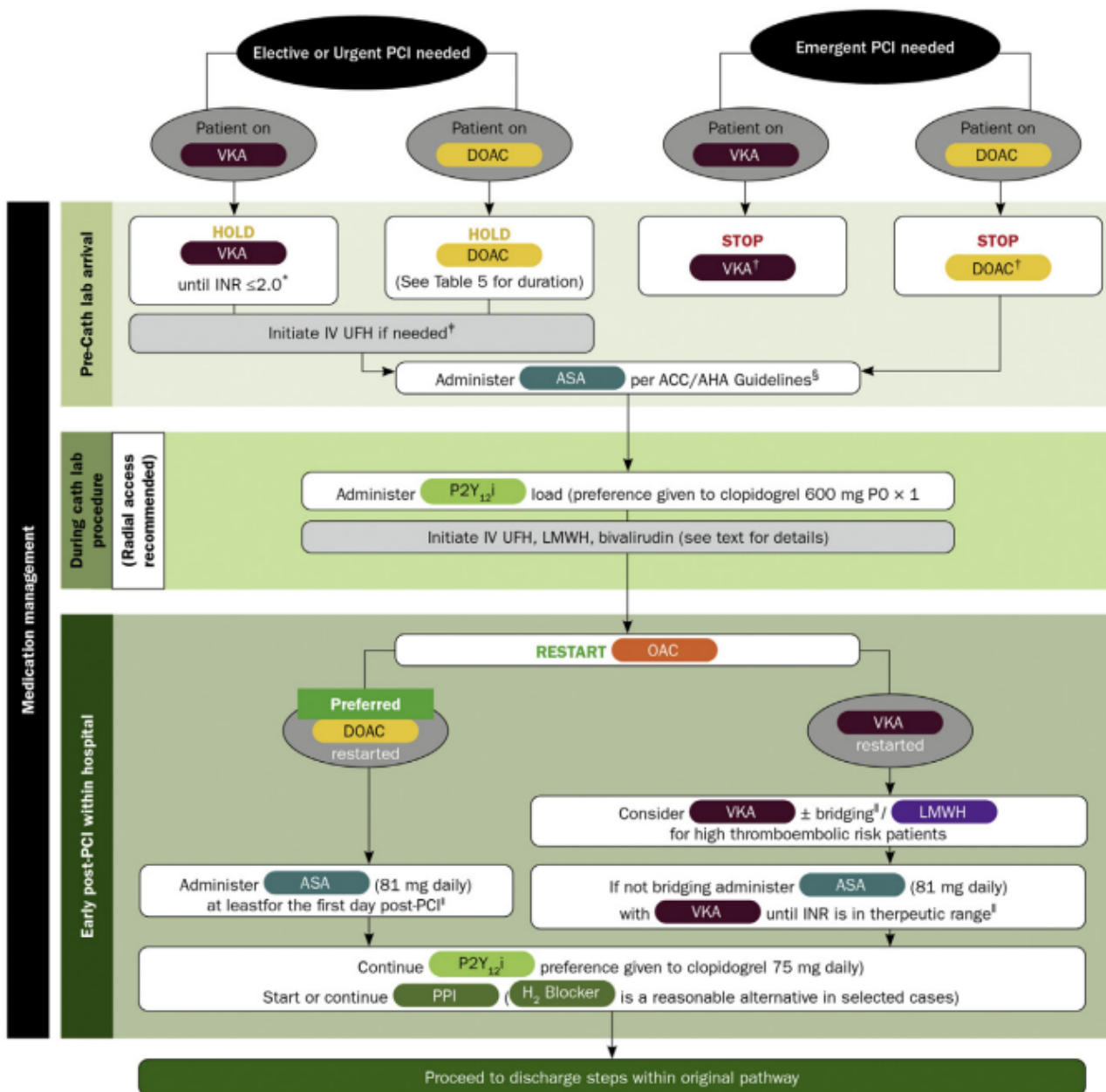
† Specific reversal agents can be considered.

‡ IV UFH should be initiated prior to cath lab arrival for those awaiting urgent PCI for an NSTEMI-ACS while no longer on therapeutic anticoagulation.

§ ASA 325 mg \times 1 for elective PCI; ASA 162-324 mg \times 1 for urgent/emergent PCI.

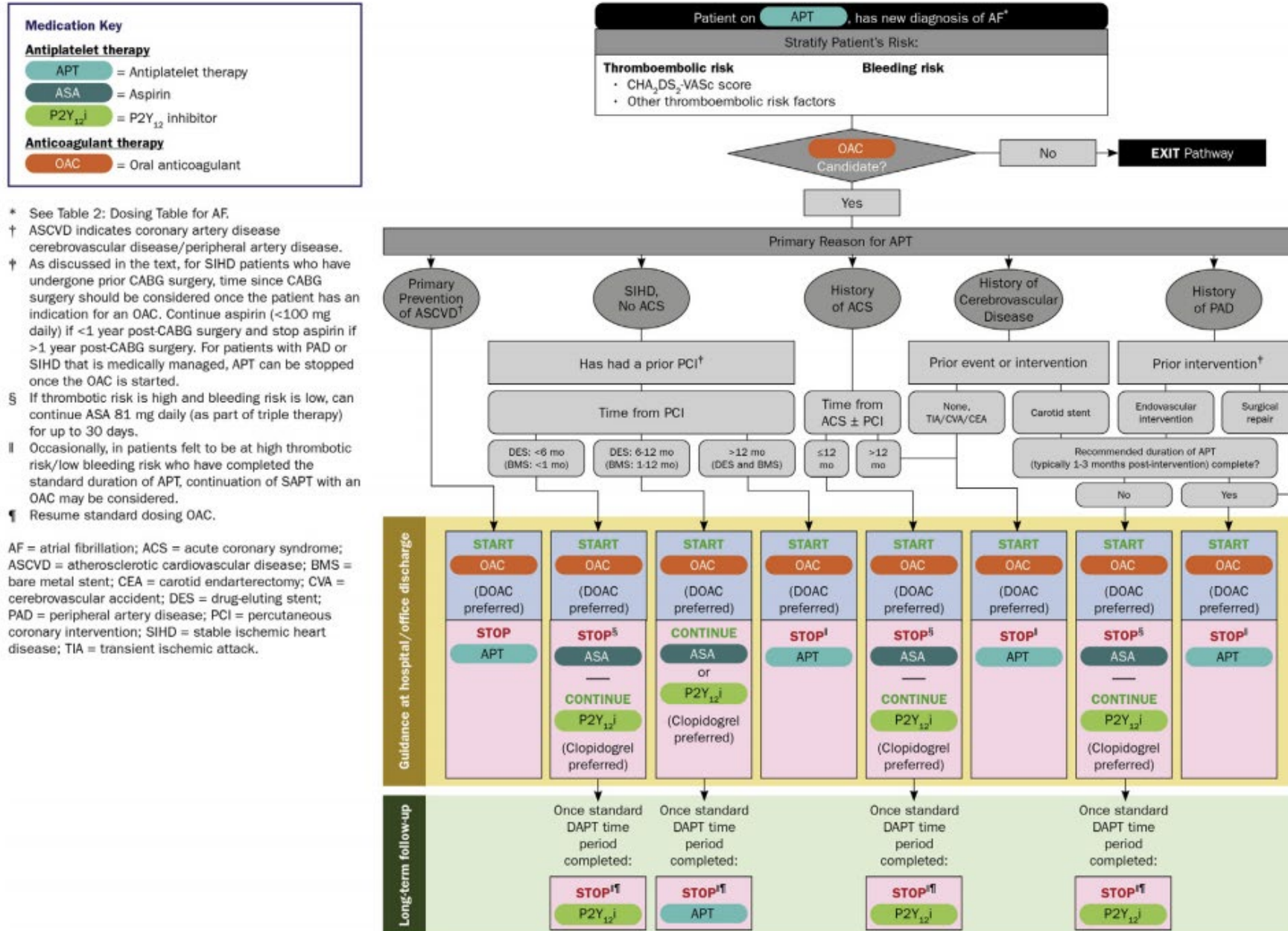
|| If thrombotic risk is high and bleeding risk is low, can continue ASA 81 mg daily (as part of triple therapy) for up to 30 days.

INR = international normalized ratio; IV = intravenous; NSTEMI-ACS = non-ST-elevation acute coronary syndrome; PCI = percutaneous coronary intervention; UFH = unfractionated heparin.



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FIGURE 4 Patient on APT With a New Diagnosis of AF: Discharge and Long-Term Management of Antithrombotic Therapy



Check out the additional ECD Figures

- Figure 5: Patient with Prior VTE Being Considered for PCI: Peri-PCI and Hospital Discharge Management of Antithrombotic Therapy
- Figure 6a and 6b: Patient With VTE on AC Who Has Undergone PCI
- Figure 7: Patient on APT With New VTE: Management of Initial Antithrombotic Therapy at Discharge

Q&A



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Announcements & Important Dates

- Call for Quality Summit Abstracts: Abstract Submission deadline is 11:59 PM ET on ***Wednesday, June 30, 2021***
- Dashboard active until **August 31, 2021**
- Listserv active until **August 31, 2021**
- ACC Quality Summit will be virtual **September 29- October 1, 2021**
- Assessment, Toolkit and Webinars will remain available to all registry participants



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2020 Quality Summit: 1st Place



Hackensack
Meridian Health
Ocean Medical Center

Reducing Bleeding Risk In Cath Lab Patients

Author: Sara Belajonas, MSN, RN, APN-C, CCRN, CCCC No disclosures

Co Author:

Jeanne Jacobus, MSN, RN



Hackensack
Meridian Health
Ocean Medical Center

BACKGROUND

OMC is a 317-bed community hospital in Ocean County, New Jersey. It is a member of the Hackensack Meridian Health system which includes 17 hospitals in northern, central and southern New Jersey. OMC is an Accredited Chest Pain Center with PCI by the American College of Cardiology Accreditation Services since 2006 and has participated in the National Cardiovascular Data Registry (NCDR®) since 2012. The Acute Coronary Syndrome (ACS) Committee is an interdisciplinary committee that reviews multiple processes as well as NCDR® metrics relating to the care of the acute myocardial infarction patient. Monthly, ACC accreditation metrics, NCDR® data outcomes, and best practice initiatives are discussed.

Bleeding is a known risk associated with percutaneous coronary intervention (PCI). The American College of Cardiology Foundation initiated the PCI Bleed Quality Campaign to provide resources, support and training to promote best practice and improve patient outcomes. In review of Ocean Medical Center's (OMC) National Cardiovascular Data Registry (NCDR®) CathPCI data, the PCI in-hospital risk standardized bleeding was revealed to be below the 50th percentile. This revelation uncovered an opportunity to reduce patient risk and improve outcomes.

PRELIMINARY FINDINGS

In September of 2019, OMC's Acute Coronary Syndrome Committee (ACS) reviewed NCDR CathPCI metrics. The 2018 Q4 report revealed that metric 40-PCI in-hospital risk standardized bleeding was 3.15%. This resulted in the need for a process improvement initiative to decrease risk to our patients.

INITIAL DATA



METHODOLOGY

The process improvement method that was used in this project is the **Plan-Do-Study-Act (PDSA)**.



INITIATIVES

The process improvement (PI) plan was presented to the ACS committee and cardiac subsection committee for approval in October 2019. The PI initiative was then initiated in November with the following initiatives:

- Re-education and increase in awareness of patient risk.
- Initial Process change to include CV NP calculating bleeding risk score utilizing the ACC PCI bleeding Risk calculator prior to diagnostic Cardiac Cath.
- After 1st pilot month, Cath Lab RN's to adopt process and CV NP to audit tool.
- Interventionalist notified of high score >3.3%.
- Radial first approach for all high scores.
- Bleeding risk score and supporting data documented on tool.

RESULTS

- The NCDR CathPCI registry metric #40 revealed OMC increased to above the 90th percentile for 2019 Q3 with a PCI in-hospital risk standardized bleeding of 1.34%.
- Increase to 100% radial access utilization for patients with a high bleeding risk score (May 2019).



CONCLUSION

Reducing bleeding risk in our patients is a continued process improvement initiative.

Ocean Medical Center is a primary PCI facility. Patients have an expected risk due to the emergent nature of the diagnosis and associated procedure. Implementation of the bleeding risk tool has increased awareness in the prevention of bleeding complications. Calculating bleeding risk on all Cath patients increases the safety of the procedure and potential future procedures at a tertiary facility. OMC is in a good position to be granted elective PCI. Initiating strategies such as bleeding risk scoring helps to prepare our facility for elective PCI procedures.

NEXT STEP

1. Adoption of ultrasound guided femoral access
2. Continuation of the following:
 - Utilize bleeding risk calculator, associated reporting, and strategies
 - Review of all bleeding complications by Medical Director, quality dept., and peer review committee
 - Reinforcement for radial first approach
 - Data drilldown by CV NP and Data Base Administrator
 - Case review with Cath lab staff to identify opportunities
 - Report metrics to ACS committee
 - Monitor for observed bleeding education on bleeding avoidance strategies

Bleeding Risk Calculator



Ocean Medical Center (OMC)
Chest Pain - MI Registry™

Ocean Medical Center was the recipient of the 2019 Chest Pain- MI Registry® Performance Achievement Platinum Award and is an accredited Chest Pain Center by the American College Of Cardiology



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Special thanks to the Cath Lab Staff at Ocean Medical Center for their dedication and support of this project

2020 Quality Summit: People's Choice



Identification and Mitigation of Post-PCI Bleed Risk Factors Using Data From the National Cardiac Data Registry and PCI Bleed Risk Calculator

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Jackson-Madison County
General Hospital

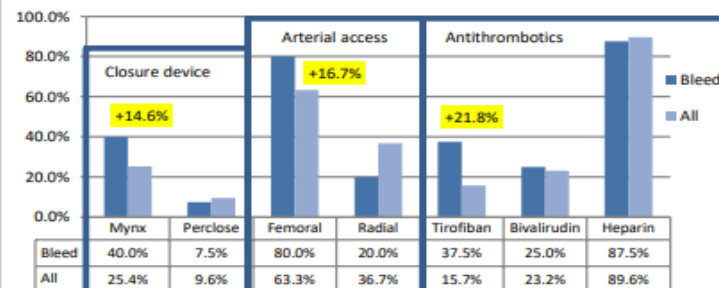
Introduction and Purpose

- In-hospital risk standardized bleeding is Metric 40 in the National Cardiac Data Registry (NCDR) CathPCI Registry *.
- In the rolling four quarters (R4Q) ending in the first quarter of 2018 our institution ranked below the 25th percentile nationally in Metric 40.
- The purpose of this study was to identify which aspects of care were associated with increased bleeding events then explore methods to avoid those factors.

Methods

- A multidisciplinary team was formed to address post-PCI bleeding rate (see Methods section for team members and roles).
- Forty patients were identified from NCDR database that experienced a bleeding event during the three quarters ending in the first quarter of 2018.
- Analyzed several aspects of care and patient characteristics with three aspects of care identified as possible high-risk factors:
 - Closure device usage (specifically the Mynx device)
 - Arterial access site (specifically femoral access)
 - Intra-procedural antithrombotics (specifically tirofiban, bivalirudin, and heparin)
- Rate of those three factors in patients that bled was compared to total PCI population during same timeframe (see Figure 1).
- No patients were excluded from either the bleed or total PCI population.

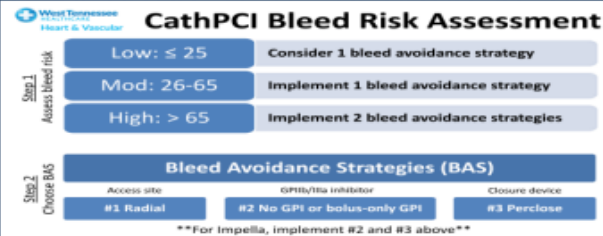
Figure 1. Bleed Risk Factor Incidence



- Mynx closure device, femoral artery access, and tirofiban usage were all determined to be high-risk and associated with increased usage in patients that bled compared to the total PCI population.
- Using this information the PCI bleed risk calculator was integrated into the electronic medical record (EMR) and a PCI bleed avoidance strategy (BAS) policy was implemented (see Central Illustration).
- The three bleed avoidance strategies were
 - 1) Perclose ProGlide closure device
 - 2) Avoid or bolus-only glycoprotein IIb/IIIa inhibitor (tirofiban)
 - 3) Radial arterial access

Methods continued in right column

Central Illustration



Results

Figure 2. High Bleed Risk Factor Usage

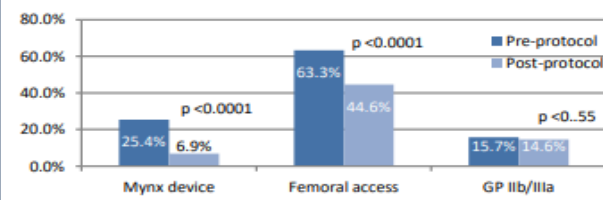


Table 1. Bleeding Rate and Anticoagulant Usage

Characteristics	Pre-protocol (n=1061)	Post-protocol (n=601)	P-value
Metric 40, in-hospital risk standardized bleeding	4.20	2.26	N/A
Bivalirudin	246 (23.2)	32 (5.3)	<0.0001
Heparin	951 (89.7)	575 (95.7)	<0.0001

Data are presented as number of subjects (percent)

Table 2. Baseline Characteristics

Characteristics	Pre-protocol (n=1061)	Post-protocol (n=601)	P-value
Age	62.9 ± 11.7	64.0 ± 11.2	NS [†]
Male gender	707 (66.7)	422 (70.2)	NS
Race			
Caucasian	898 (84.6)	524 (87.3)	NS
African American	148 (13.9)	66 (11.0)	
Other	15 (1.4)	10 (1.7)	
BMI	30.5 ± 7.0	30.6 ± 6.9	NS
Prior PCI	308 (29.0)	270 (44.9)	<0.0001
STEMI	179 (16.9)	117 (19.5)	NS

Data are presented as number of subjects (percent) or mean ± SD as appropriate
†NS = Not significant

Methods (Cont'd)

- Patients were assessed for bleeding pre-PCI and determined to be:
 - Low risk (<2.5% chance of bleeding)
 - Moderate risk (2.5-6.5%)
 - High risk (>6.5%) for bleeding
- Based on a patient's risk, cardiologists were asked to *consider* using one BAS (low risk), *implement* one BAS (mod risk), and *implement* two BAS (high risk).
- Roles of team members
 - Cardiologist – wrote the PCI BAS policy and helped with committee approval
 - Nurse and cath lab leadership – pulled NCDR data, identified the high bleed risk factors at the outset, guided the integration of the PCI bleed risk calculator into the EMR, and revised the PCI BAS policy
 - Data abstractors – educated regarding NCDR definitions
 - Pharmacist – compiled and analyzed the data from NCDR and wrote the PCI BAS policy
- Data was collected from before and after the implementation of the BAS protocol.
- All patients that underwent PCI during qualifying timeframe were included, none excluded
- Pre-BAS protocol group: July 2017 through March 2018
- Post-BAS protocol group: October 2019 through March 2020

Results

- There were 1061 patients in the pre-BAS group and 601 in the post-BAS group
- Baseline characteristics were evenly balanced between the two groups except for significantly more patients having a history of prior PCI in the post-BAS group.
- There was a significant decrease in the usage of the Mynx device (25.4% vs. 6.9%) and femoral access (63.3% vs. 44.6%) and slightly less tirofiban usage (15.7% vs. 14.6%) in the post-BAS group (Figure 2).
- In-hospital risk standardized bleeding rate decreased from 4.2 to 2.26 (Table 1).

Value Proposition

- Most importantly the project improved patient outcomes by helping to decrease bleeding risk. Fewer bleeding events lower cost of care by decreasing additional procedures and therapies such as blood products as well as limiting length of stay.

Conclusions

- This project identified three high-risk factors in the care of our PCI patients regarding bleeding: Mynx closure device usage, tirofiban usage, and femoral arterial access.
- This was addressed by integrating a PCI bleed risk calculator into the EMR and implementing a PCI bleed avoidance strategy policy.
- As a result there was a significant decrease in usage of these high-risk factors and a decrease in in-hospital risk standardized post-PCI bleeding.

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Disclosures

Dylan Wilson, PharmD; Jennifer Varner, RN, BSN– nothing to disclose



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