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
Agenda

• Campaign Updates
• Introduction of the New Campaign Tool
• Q&A
• Announcements
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
Reduce the Risk: PCI Bleed Toolkit
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)
Reduce the Risk: PCI Bleed Toolkit

- **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)**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Tools</th>
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</thead>
<tbody>
<tr>
<td>Metric 1: in-hospital risk-standardized rate of bleeding events for all PCI patients</td>
<td>General Considerations for Anticoagulation and Antiplatelet Therapy in PCI</td>
</tr>
<tr>
<td>Metric 4: Anticoagulation utilization</td>
<td>Expert Consensus Decision Pathway for Periprocedural Management of Anticoagulation in Patients With NVAF</td>
</tr>
<tr>
<td>Metric 1: in-hospital risk-standardized rate of bleeding events for all PCI patients</td>
<td>2020 ACC Expert Consensus Decision Pathway for Anticoagulant and Antiplatelet Therapy in Patients With Atrial Fibrillation or Venous Thromboembolism Undergoin</td>
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</tbody>
</table>
**Figure 2: Assessing Bleed Severity and Managing Major and Non-Major Bleeds**

**Does 1 of the Following Factors Apply?**
- Bleeding at a critical site (see Table 1)
- Hemodynamic instability
- Clinically overt bleeding with hemoglobin decrease ≥2 g/dL or administration of ≥2 units RBCs

**Bleed is considered major**

- Is the bleed at a critical site or life threatening?
  - Yes
    - Stop OAC and antithrombotic agents
    - If patient is on a VKA, give 5-10 mg IV vitamin K
    - Provide local therapy/manual compression
    - Provide supportive care and volume resuscitation
    - Assess for and manage comorbidities that could contribute to bleeding (e.g., thrombocytopenia, uremia, liver disease)
    - Consider surgical/procedural management of bleeding site
  - No
    - Suggest administering reversal/hemostatic agents (see Figure 3)

- Did the above measures control the bleed?
  - Yes
    - Stop OAC
    - Provide local therapy/manual compression
    - If patient is on a VKA, give 5-10 mg IV vitamin K
    - Provide supportive care and volume resuscitation
    - Assess for and manage comorbidities that could contribute to bleeding (e.g., thrombocytopenia, uremia, liver disease)
    - Consider surgical/procedural management of bleeding site
  - No
    - Did the above measures control the bleed?
      - Yes
        - Stop OAC
        - Provide local therapy/manual compression
        - If patient is on a VKA, give 5-10 mg IV vitamin K
        - Provide supportive care and volume resuscitation
        - Assess for and manage comorbidities that could contribute to bleeding (e.g., thrombocytopenia, uremia, liver disease)
        - Consider surgical/procedural management of bleeding site
      - No
        - Consider continuing OAC (provided there is an appropriate indication)
        - Provide local therapy/manual compression
        - If patient is on concomitant antithrombotic therapy, assess risks and benefits of stopping
        - Assess for and manage comorbidities that could contribute to bleeding (e.g., thrombocytopenia, uremia, liver disease)
        - Determine if dosing of OAC is appropriate

**Bleed is considered non-major**

- Does the bleed require hospitalization, surgical/procedural intervention, or transfusion?
  - Yes
    - Stop OAC
    - Provide local therapy/manual compression
    - If patient is on a VKA, give 5-10 mg IV vitamin K
    - Provide supportive care and volume resuscitation
    - Assess for and manage comorbidities that could contribute to bleeding (e.g., thrombocytopenia, uremia, liver disease)
    - Consider surgical/procedural management of bleeding site
  - No
    - Suggest administering reversal/hemostatic agents (see Figure 4)

**Definitions**
- OAC: direct-acting oral anticoagulant
- IV: intravenous
- OAC: oral anticoagulant, including DOACs and VKAs
- PCCs: prothrombin complex concentrate
- PO: per os (by mouth)
- RBCs: red blood cells
- VKA: vitamin K antagonist
- Reversal/hemostatic agents include reversal strategies such as PCCs, plasma, vitamin K, and specific reversal agents for DOACs (e.g., idarucizumab for dabigatran,andexanet alf for apixaban or rivaroxaban).
FIGURE 4 Considerations for Restarting Anticoagulation

DOES >1 OF THE FOLLOWING CLINICAL INDICATIONS APPLY?
- Nonvalvular AF with CHA2DS2-VASc score <2 in men and <3 in women
- Temporary indication for OAC (e.g., post-surgical prophylaxis, OAC after an anterior MI without left ventricular thrombus, post-LAA closure device placement)
- Recovered acute stress cardiomyopathy (e.g., Takotsubo cardiomyopathy)
- First-time provoked VTE >3 months ago
- Bioprosthetic valve placement in the absence of AF >3 mos ago

Suggest discontinuing anticoagulation

DOES >1 OF THE FOLLOWING FACTORS APPLY?
- Bleed occurred at a critical site (see Table 1)
- Patient is at high risk of rebleeding or of death/disability with rebleeding
- Source of bleed has not yet been identified
- Surgical/invasive procedure planned
- After informed discussion, patient declines or does not wish to restart OAC at this time (see Table 7)

Suggest delaying restart of anticoagulation (see Figure 6)

Suggest restarting anticoagulation (see Figure 5)

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

**Medication Key**

- **Antiplatedlet therapy**
  - ASA = Aspirin
  - P2Y12 = 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 infection or death. For stable inpatients, the procedure is performed during hospitalization for coronary artery, NOT because it is urgent or emergent.

**Urgent:** Procedure should be performed on an inpatient basis prior to discharge due to significant risk of ischemic, hemorrhagic, 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 canceling 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.

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

5 Specific reversal agents can be considered.

6 IV UFH should be initiated prior to each lab arrival for those awaiting urgent PCI for an NSTEMI ACS who no longer on therapeutic anticoagulation.

7 ASA 325 mg x 1 for elective PCI; ASA 162-324 mg x 1 for urgent emergent PCI.

8 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.

- **Early post-PCI within hospital**
  - PREPARED: DOAC preferred
  - SELECTED: VKA

- **Prep lab arrival**
  - Hold VKA until INR ≤2.0

- **Emergency PCI needed**
  - STOP VKA

- **HOLD DOAC (See Table 5 for details)**

- **Initiate IV UFH if needed**

- **Administer ASA per ACC/AHA Guidelines**

- **Dilute lab notification**

- **Prep tab arrival**

- **Restart DOAC**

- **TO STOP**

- **Consider VKA a bridging for high thromboembolic risk patients**

- **If not bridging administer**

- **Consider ASA 81 mg daily**

- **Consider LMWH**

- **Proceded to discharge within original pathway**

- **(Preference given to clopidogrel 75 mg daily)**

- **H2 Blocker (Is a reasonable alternative in selected cases)**
FIGURE 4  Patient on APT With a New Diagnosis of AF: Discharge and Long-Term Management of Antithrombotic Therapy

Medication Key

<table>
<thead>
<tr>
<th>Antithrombotic therapy</th>
<th>APT</th>
<th>ASA</th>
<th>P2Y12 inhibitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>APT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASA</td>
<td></td>
<td></td>
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</tr>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anticoagulant therapy</th>
<th>OAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>OAC</td>
<td></td>
</tr>
</tbody>
</table>

† See Table 2: Dosing Table for APT

‡ ASCVD indicates coronary artery disease/cerebrovascular disease/peripheral artery disease.

∥ As discussed in the text, for SMD patients who have undergone prior CABG surgery, time since CABG surgery should be considered when the patient has an indication for an OAC. Continue aspirin (<100 mg daily) if <5 years post-CABG surgery and stop aspirin if >1 year post-CABG surgery. For patients with PAD or SMD that is medically managed, APT can be stopped once the OAC is initiated.

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

II Occasionally, in patients felt to be at high thrombotic risk/low bleeding risk who have completed the standard duration of APT, continuation of SAPT with an OAC may be considered.

Resume standard dosing OAC.

AF = atrial fibrillation; ACS = acute coronary syndrome; ASCVD = atherosclerotic cerebrovascular disease; BMS = bare metal stent; CEA = carotid endarterectomy; CVA = cerebrovascular accident; DES = drug-eluting stent; PAD = peripheral artery disease; PCI = percutaneous coronary intervention; SMD = stable ischemic heart disease; TIA = transient ischemic attack.
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
• 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
Reducing Bleeding Risk in Cath Lab Patients

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

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 2009 and has participated in the National Cardiovascular Data Registry (NCORP®) since 2012. The Acute Coronary Syndromes (ACS) Committee is an interdisciplinary committee that reviews multiple processes as well as NCORP® metrics relating to the care of the acute myocardial infarction patient. Monthly ACC accredited metrics, NCORP® 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 promote resources, support and training to promote best practice and improve patient outcomes. In review of Ocean Medical Center’s (OMC) National Cardiovascular Data Registry (NCORP®) CathPCI data, the PCI in-hospital risk standardized bleeding was revealed to be below the 56th percentile. This revelation uncovered an opportunity to reduce patient risk and improve outcomes.

INITIAL DATA

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 subsnaces committee for approval in October 2019. The PI initiative was then initiated in November with the following initiatives:
- Reeducation and increased 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 RNs to adopt process and CV NP to audit tool.
- Interventionist notified of high score >3.3.
- Radial first approach for all high scores.
- Bleeding risk score and supporting data documented on tool.

PRELIMINARY FINDINGS

In September of 2019, OMC’s Acute Coronary Syndrome Committee (ACS) reviewed NCORP® CathPCI data. The 2018 Q4 report revealed that 69 PCI in-hospital risk standardized bleeding was 3.19%. This resulted in the need for a process improvement initiative to decrease risk to our patients.

SUBJECTIVE FINDINGS

The process improvement model utilized in this project is the Plan-Do-Study-Act (PDSA).

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 appropriating strategies such as radial bleeding scoring helps to prepare our facility for elective PCI procedures.

REFERENCES


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Special thanks to the Cath Lab Staff at Ocean Medical Center for their dedication and support of this project.
Identification and Mitigation of Post-PCI Bleed Risk Factors Using Data From the National Cardiac Data Registry and PCI Bleed Risk Calculator

Dylan Wilson, Pharm.D., BCPS; Jennifer Varner, RN, BSN
Jackson-Madison County General Hospital – Jackson, Tennessee

Method:
A multiprofessional team was formed to address post-PCI bleeding rate (see Methods section for team members and roles). Forty patients were identified from NCDB data that experienced a bleeding event during the three quarters ending in the first quarter of 2018. Table 1 identifies patients who bled compared to total PCI population during same timeframe (see Figure 1). All patients were excluded from the bleed or total PCI population.

Figure 1. Bleed Risk Incidence

Introduction and Purpose
• In-hospital risk standardized bleeding is defined in the National Cardiac Data Registry (NCDB) as the PCI Registry.
• In the rolling four quarters (R4Q) ending in the first quarter of 2018 our institution ranked within 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 and then explore methods to avoid those factors.

Methods
A multiprofessional team was formed to address post-PCI bleeding rate (see Methods section for team members and roles).

- Forty patients were identified from NCDB data that experienced a bleeding event during the three quarters ending in the first quarter of 2018.
- Table 1 identifies patients who bled compared to total PCI population during same timeframe (see Figure 1). All patients were excluded from the bleed or total PCI population.

Figure 2. High Bleed Risk Factor Usage

<table>
<thead>
<tr>
<th>Bleed Risk Factors</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closure device</td>
<td>12.5%</td>
</tr>
<tr>
<td>Myocardial repair</td>
<td>3.5%</td>
</tr>
<tr>
<td>Percutaneous</td>
<td>25.3%</td>
</tr>
<tr>
<td>Radial arterial</td>
<td>13.7%</td>
</tr>
<tr>
<td>All</td>
<td>22.2%</td>
</tr>
</tbody>
</table>

Table 1. Bleeding Rate and Anticoagulant Usage

<table>
<thead>
<tr>
<th>Anticoagulant Usage</th>
<th>Bleeding Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warfarin</td>
<td>42%</td>
</tr>
<tr>
<td>Bivalirudin</td>
<td>32%</td>
</tr>
<tr>
<td>Hirudin</td>
<td>57%</td>
</tr>
</tbody>
</table>

Bleeding Avoidance Strategies (BAS)

- Protocol
- Pre-procedure

Results

- There were 104% patients in the pre-BAS group and 104% 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 Myocardial repair (25.4% vs. 6.7%) and femoral access (63.3% vs. 44.0%) and slightly less transfusion 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 important this project improved patient outcomes by decreasing bleeding risk.
- Fewer bleeding events lower cost of care by decreasing additional procedures and therapies such as blood products as well as a timeline benefit of stay.

Conclusions

- This project identified high-risk factors in the care of our PCI patients regarding bleeding.
- Most clinical factors used transfusion usage, and femoral arterial access.
- This was addressed by integrating a PCI bleed risk calculator into the EHR and implementing a PCI bleed avoidance strategy.
- 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.

Disclosures

Dylan Wilson, Pharm.D; Jennifer Varner, RN, BSN - nothing to disclose