SCAI Quality Improvement Toolkit

Working on QUALITY, One Cath Lab at a Time

www.SCAI.org/QIT
The SCAI Quality Improvement Toolkit was developed with support from Daiichi Sankyo and Lilly. The Society gratefully acknowledges this support, while taking sole responsibility for all content developed and disseminated through this effort.
Vision

“We have talked for a number of years about the need for interventionalists to “own” the QI process in the cath lab.

SCAI QIT offers a unique opportunity for SCAI members to demonstrate their commitment to improving quality of care and to reassure our patients that their expectations of receiving the highest quality of care in the cath lab are being met.

It’s time for you to get involved. It’s time for you to get to work.”

– Christopher J. White, MD, MSCAI
Outline

- Defining Quality in the Cath Lab
- Operator and Staff Requirements
- Procedural Quality
- 2016 Cath Lab Best Practices
- Facility and Environmental Issues
- Care Coordination with Referring Physicians
Care Coordination with Referring Physicians
Purpose

◦ To provide education to the referring physician on common pre- and post-procedural issues in patients undergoing invasive/interventional CCL procedures
◦ To foster a collaborative effort regarding our mutual patients in the important area of aftercare

Intended Audience

◦ Primary Care/Referring physicians, interventionalists, nurses, advanced practice providers, SCAI QIT Champions
Contrast-Induced AKI

- **Class I indications** are to assess risk of CI-AKI before PCI, provide adequate hydration, and minimize volume of contrast media
  - QxMD.com Contrast Nephrology Post PCI Calculator
  - **PCI Risk Assessment Tool**
  - Contrast volume (CV) > 3.7 x CrCl is predictive of AKI
- N-acetyl-L-cysteine (mucomyst) is **not useful**
- **Metformin**: discontinue 24 hrs prior, check Cr 48 hrs after prior to restarting
- **ACE-I**: May need to be held in patients with low CrCl/GFR

Gurm HS et al. J Am Coll Cardiol. 2011;58(9):907-14
Laskey WK et al. J Am Coll Cardiol. 2007;50:584-590

www.SCAI.org/QIT
Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate steroid and antihistamine prophylaxis before repeat contrast administration

- **Example**: Oral Prednisone 50mg at 13, 7, and 1 hr prior with 50mg of oral diphenhydramine 1 hr prior to the procedure

- **Shellfish allergy** is not a predictor of contrast reactions and **does not** require pre-treatment
Assessing Bleeding Risk

- All patients should be evaluated for risk of bleeding before PCI
  - **SCAI PCI Risk Assessment Tool**
  - **Cath PCI: Bleeding Model (Risk Adjusted) Specifications/Testing Overview**

- Coumadin held; INR should be < 1.8
- Dabigatran/rivaroxaban/edoxaban/apixaban held 1-2 days prior; dependent on GFR
- UFH/LMWH bridging likely necessary in patients with mechanical prosthetic valves

- WOEST: Triple therapy vs. clopidogrel/warfarin (no ASA) after PCI with need for ongoing anticoagulation (AF, mech. valve)*
  - Bleeding complications on “triple therapy” = 44.9% vs. 19.4% for “double-therapy”
  - No increase in rate of thrombotic events in “double therapy” group
  - Less all-cause mortality in “double therapy” group

*Lancet 2013;381:1107-15*
Aspirin dosing
- 81mg daily after PCI, range is 75-100mg

P2Y12 Inhibitor and duration (with ASA)
- **BMS or DES during PCI for ACS**: DAPT should be given for at least 12 months (options include: clopidogrel 75 mg qd, prasugrel 10 mg qd, or ticagrelor 90 mg bid)
- **2nd gen DES for a non–ACS indication**: clopidogrel 75 mg qd should be given for at least 6 months if patients are not at high risk of bleeding
- **BMS for a non-ACS indication**, clopidogrel should be given for a minimum of 1 month

Earlier Discontinuation reasonable in patients treated with DAPT after 2nd gen DES who develop a high risk of bleeding (e.g., treatment with oral anticoagulant therapy), at high risk of severe bleeding complication (e.g., major intracranial surgery), or develop significant overt bleeding; discontinuation of P2Y12 inhibitor therapy after 3 months for SIHD or after 6 months for ACS may be reasonable.
EDS = 2nd generation DES

Levine GN et al, JACC 2016.
2016 ACC/AHA Focused Update on Duration of Dual Antiplatelet Therapy
Shorter-duration DAPT can be considered for patients at lower ischemic risk with high bleeding risk, whereas longer-duration DAPT may be reasonable for patients at higher ischemic risk with lower bleeding risk.

<table>
<thead>
<tr>
<th>Increased Ischemic Risk/Risk of Stent Thrombosis (may favor longer duration DAPT)</th>
<th>Increased Bleeding Risk (may favor shorter duration DAPT)</th>
</tr>
</thead>
</table>
| Increased Ischemic Risk | History of prior bleeding  
Oral anticoagulant therapy  
Female sex  
Advanced age  
Low body weight  
CKD  
Diabetes mellitus  
Anemia  
Chronic steroid or NSAID therapy |
| Advanced age  
ACS presentation  
Multiple prior MI  
Extensive CAD  
Diabetes mellitus  
CKD |  
| Increased Risk of Stent Thrombosis |  
ACS presentation  
Diabetes mellitus  
Left ventricular ejection fraction <40%  
First generation drug-eluting stent  
Stent under-sizing or under-deployment  
Small stent diameter or greater stent length  
Bifurcation stents  
In-stent restenosis |
DAPT Score

Analysis of DAPT Study suggests that in patients treated for 1 year with DAPT and without significant bleeding or ischemic events, subsequent use of the “DAPT Score” can be helpful in assessing the benefit/risk ratio with prolonged DAPT

- A score of $\geq 2$ was associated with a favorable benefit/risk ratio for prolonged DAPT, while a score of $< 2$ was associated with an unfavorable benefit/risk ratio.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age $\geq$75</td>
<td>-2</td>
</tr>
<tr>
<td>Age 65 - &lt;75</td>
<td>-1</td>
</tr>
<tr>
<td>Age &lt;65</td>
<td>0</td>
</tr>
<tr>
<td>Current cigarette smoker</td>
<td>1</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1</td>
</tr>
<tr>
<td>MI at presentation</td>
<td>1</td>
</tr>
<tr>
<td>Stent diameter $&lt;3$mm</td>
<td>1</td>
</tr>
<tr>
<td>Paclitaxel-eluting stent</td>
<td>1</td>
</tr>
<tr>
<td>CHF or LVEF$&lt;30$%</td>
<td>2</td>
</tr>
<tr>
<td>Saphenous vein graft PCI</td>
<td>2</td>
</tr>
</tbody>
</table>

Assess ischemic and bleeding risks using validated risk predictors (e.g., CHA2DS2-VASc, HAS-BLED)

Keep triple therapy duration **as short as possible**; dual therapy only (oral anticoagulant and clopidogrel) may be considered in select patients

Consider a target **INR of 2.0-2.5** when warfarin is used

**Clopidogrel** is the P2Y12 inhibitor of choice

Use low-dose (≤100 mg daily) aspirin

PPIs should be used in patients with a history of gastrointestinal bleeding and are reasonable to use in patients with increased risk of gastrointestinal bleeding
Newer Antiplatelet Agents

- **Prasugrel**: contraindicated in patients with prior stroke; caution in patients $\geq 75$ years old and low body weight $<60$kg (consider lower dose prasugrel 5mg daily instead of 10mg daily)

- **Ticagrelor**: must use with aspirin dose $<100$mg daily

- **Cangrelor**: An IV P2Y12 inhibitor for adjunct use during PCI. An oral P2Y12 inhibitor loading dose must be given immediately after discontinuation* to maintain inhibition for chronic treatment

* Ticagrelor can be given during or immediately after discontinuing cangrelor infusion
PPIs and Antiplatelet Therapy

- PPI should be used in patients with history of prior GI bleeding who require DAPT

- **PPI use is reasonable in patients with increased risk of gastrointestinal bleeding** (advanced age, concomitant use of warfarin, steroids, nonsteroidal anti-inflammatory drugs, H. pylori infection, etc.) who require DAPT

- **Routine use of a PPI is not recommended** for patients at low risk of gastrointestinal bleeding, who have much less potential to benefit from prophylactic therapy

---

Care Coordination with Referring Physicians
Findings do not support the need to avoid concomitant use of PPIs for gastric protection in patients receiving thienopyridine therapy who are at increased risk for GI bleeding.
### Association between type of PPI and Outcomes?

<table>
<thead>
<tr>
<th>PPI</th>
<th>$K_i$ (uM)(CYP2C19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lansoprazole</td>
<td>0.45</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>6.2</td>
</tr>
<tr>
<td>Esomeprazole</td>
<td>8.6</td>
</tr>
<tr>
<td>Rabeprazole</td>
<td>21.3</td>
</tr>
<tr>
<td>Pantoprazole</td>
<td>69.4</td>
</tr>
</tbody>
</table>

Although Pantoprazole is a weaker inhibitor of CYP2C19, no independent association was found in TRITON-TIMI 38 between use of these drugs and the risk of MI or the composite of CV death, MI, or stroke.
Provided reassurance that there is no clinically relevant CV interaction between PPI’s and clopidogrel

Called into question the utility of platelet reactivity assays

**The COGENT Trial: Implications**

---

**THE WALL STREET JOURNAL.**

**HEALTH INDUSTRY | OCTOBER 7, 2010**

**Worris About Using Plavix With Heartburn Pills May Be Overblown**

By RON WINSLOW

Worries over the risk of combining the blockbuster blood thinner Plavix with certain heartburn pills may be overblown, a new study suggests.
Peri-procedural DAPT: Recommendations

- For **elective** procedures, **await completion of DAPT**
  - 1 month minimum for BMS
  - 6 months minimum for 2nd gen DES. Consider 3-6 months if delayed surgery risk >> stent thrombosis risk

- For **emergent or urgent surgeries**, discuss with surgeon to consider if willing to operate on DAPT. If the bleeding risk is significant, then:
  - Stop antiplatelet agent for as short a period as is reasonable
  - ASA 81 mg daily peri-procedurally
  - Restart antiplatelet agent as soon as possible post procedure

- **No proven benefit to “bridging”** with either IIb/IIa inhibitors or unfractionated heparin/LMWH

---

DAPT*: Elective Noncardiac Surgery

*2nd generation DES

Levine GN et al, JACC 2016.
2016 ACC/AHA Focused Update on Duration of Dual Antiplatelet Therapy
DAPT Duration Debate

- Prolongation of DAPT necessitates a fundamental tradeoff between ↓ ischemic risk and ↑ bleeding risk.
- Decisions about duration of DAPT require a thoughtful assessment of the benefit/risk ratio, integration of study data, and consideration of patient preference, interventionalist, and referring provider.
- In studies of prolonged DAPT after DES implantation or after MI, duration of therapy was limited to several years. Thus, in patients for whom the benefit/risk ratio favors prolonged therapy, the true optimal duration of therapy is unknown.

Levine GN et al, JACC 2016.
2016 ACC/AHA Focused Update on Duration of Dual Antiplatelet Therapy
Access Site Management

- Femoral
  - manual compression
  - vascular closure device (faster hemostasis and earlier ambulation but no different than manual compression at reducing access site complications)

- Radial
  - Lower rates of access-site bleeding
  - Shorter length of stay and lower hospital costs
  - Increased patient comfort and faster ambulation


www.SCAI.org/QIT
Pseudoaneurysms

- A contained arterial rupture with arterial communication
- Incidence: <2% (diagnostic) and 2-6% (PCI)
- Manifests as pain in the groin and a pulsatile mass
- Definitive test is duplex ultrasound and treatment usually can be performed by US-guided compression or thrombin injection. Small PSAs (<3cm) may close spontaneously

CT image demonstrating a thin-necked femoral pseudoaneurysm (PSA); ultrasound image showing “to and fro” flow of blood before and after thrombin injection.
**Arteriovenous fistula**

- Anomalous direct connection between artery and vein resulting in shunting of blood
- May present with palpable thrill or audible bruit and rarely, ischemia beyond the lesion
- Severe untreated lesions may lead to high-output cardiac failure
- Diagnosis made with duplex imaging
- If symptomatic or severe in degree vascular surgery consultation and repair is warranted
Radial artery occlusion is the most frequent complication (~3-10%).

- Majority of occlusions are asymptomatic and recanalize approximately 50% of the time.
- Symptomatic occlusions are uncommon but clinical sequela are exceedingly rare with dual circulation.
- Most common complaint is pain/discomfort in affected forearm which may be treated with supportive therapy:
  - NSAIDs
  - Warm soaks
Cardiac rehabilitation should be recommended to patients after PCI, particularly for moderate- to high-risk patients for whom supervised exercise training is warranted.

In patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable.

Routine, periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed.
Nuclear MPI, echocardiography, or CMR with either exercise or pharmacological stress can be useful for follow-up assessment at 2-year or longer intervals in patients with stable ischemic heart disease (SIHD) with prior evidence of silent ischemia or who are at high risk for a recurrent cardiac event and a) are unable to exercise to an adequate workload, b) have an uninterpretable EKG, or c) have a history of incomplete coronary revascularization.

Nuclear MPI, echocardiography, or CMR, with either exercise or pharmacological stress or CTA, is not recommended for follow-up assessment in patients with SIHD, if performed more frequently than at: (a) 5-year intervals after CABG or (b) 2-year intervals after PCI.

Fihn SD et al., JACC 2012
What About MRI Safety After Stenting?

- Ferromagnetism is the issue
- None of the currently or previously utilized coronary stents approved by FDA are significantly ferromagnetic
- Device manufacturer caveats

Levine et al, Circulation. 2007;116:2878-2891
Resources & Support

- SCAI QI Committee Assistance: Info@scai.org

- SCAI QIT Updates: http://www.scai.org/QIT/default.aspx

- SCAI QIT Tip of the Month: http://www.scai.org/QITTtip/default.aspx
Acknowledgments

- SCAI President: James C. Blankenship, MD
- SCAI QI Committee Chair/Vice-Chair: Sunil V. Rao, MD and Kalon K. Ho, MD
- Original Authors (2011 QIT): Christopher J. White, MD; Sunil V. Rao, MD; Kalon K. Ho, MD; Skip Anderson, MD; Lyndon J. Box, MD; Charlie E. Chambers, MD; Kirk N. Garratt, MD; Srihari S. Naidu, MD; Steven J. Yakubov, MD; Suresh R. Mulukutla, MD; Henry S. Jennings, MD
Acknowledgments

- 2016 QIT Update: Rajesh V. Swaminathan, MD; Jordan G. Safirstein, MD; Henry S. Jennings, MD, Jayant Bagai, MD; Craig J. Beavers, PharmD; Dmitriy N. Feldman, MD; Sunil V. Rao, MD

- 2016 Cath Lab Best Practices Expert Consensus Statement: Srihari S. Naidu, MD; Herbert D. Aronow, MD; Lyndon C. Box, MD; Peter L. Duffy, MD; Daniel M. Kolansky, MD; Joel M. Kupfer, MD; Faisal Latif, MD; Suresh R. Mulukutla, MD; Sunil V. Rao, MD; Rajesh V. Swaminathan, MD; and James C. Blankenship, MD

- SCAI Staff: Joel C. Harder, MBA