Update on STEMI Guidelines

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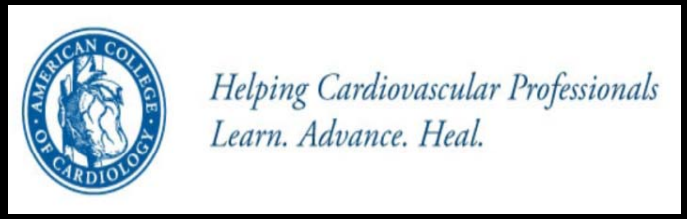
- **Advisory Board/Consulting:**
  - **Genzyme, Bayer, Baxter Healthcare, Ortho McNeil Jansen, theHeart.org, Medscape, Maquet, CSI technologies**
- **Professional Society Roles:**
  - **Member ACC/AHA AUC Task Force**
  - **Chair of Writing Group for ACC/AHA Coronary Revascularization Appropriateness Criteria**
  - **Member ACC/AHA CABG Guidelines**
  - **Chair of AHA Diagnostic and Interventional Cath Committee**

STEMI Guidelines Update – Treatment Strategies and Pharmacotherapy

- 2011 ACC/AHA PCI Guidelines for Invasive treatment strategies
- 2009 ACC/AHA STEMI Guideline Update
  - Pharmacotherapy
- Updated Trials since STEMI Update

ACC/AHA 2009 STEMI/PCI Guidelines Focused Update

Based on the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction (STEMI) and the ACC/AHA/SCAI Guidelines on Percutaneous Coronary Intervention (PCI): A Report of the ACC/AHA Task Force on Practice Guidelines



2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention (and Coronary Revascularization)

Class of Recommendation (COR)

COR	Benefit/Risk	Key Words (The procedure or treatment…)
Class I	Benefit >>>Risk	•Should be performed/administered •Is recommended •Is indicated •Is useful/effective/beneficial
Class IIa	Benefit>>Risk	•Is reasonable •Can be useful/effective/beneficial •Is probably recommended or indicated
Class IIb	Benefit ≥Risk	•May/might be considered or be reasonable •Usefulness/effectiveness is unknown/unclear/uncertain or not well established
Class III – No Benefit	•Not helpful •No proven benefit	•Is not recommended/indicated •Should not be performed/administered •Is not useful/beneficial/effective
Class III – Harm	•Harmful •Excess cost without benefit or harmful	•Potentially harmful •Causes harm •Should not be performed/administered

Level of Evidence (LOE)

LOE	Criteria
A	•Multiple populations evaluated •Data derived from multiple randomized clinical trials or meta-analyses
B	•Limited populations evaluated •Data derived from a single randomized trial or nonrandomized studies
C	•Very limited populations evaluated •Only consensus opinion of experts, case studies, or standard of care

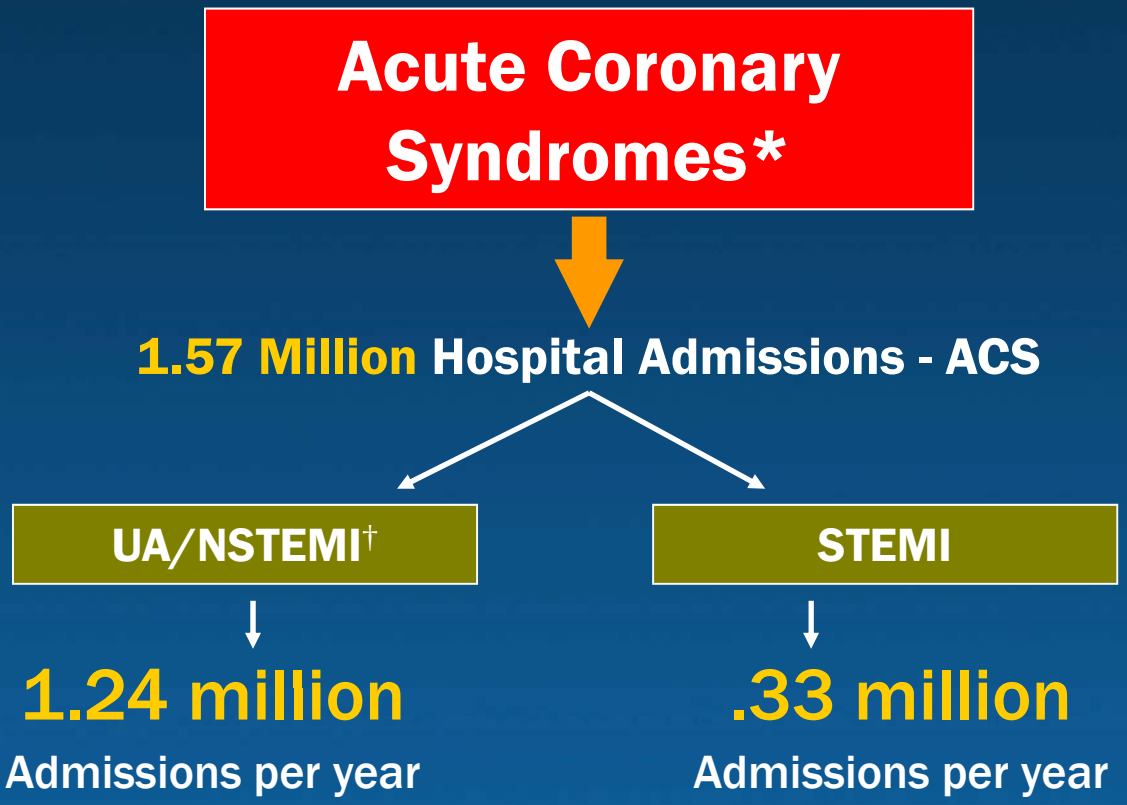
2009 Update of the STEMI and PCI Guidelines: Topics/ New Trials

- Glycoprotein IIb/IIIa inhibitors
  - On-TIME-2; Tirofiban pre-primary PCI
  - MULTISTRATEGY; STEMI Abciximab versus Tirofiban; DES vs BMS
- Thienopyridines
  - TRITON-TIMI 38; Prasugrel for ACS/STEMI
  - (PLATO) - Ticagrelor
- Anti-thrombins
  - HORIZONS-AMI; Bivalirudin
- Rescue PCI and Transfer PCI
  - CARESS-in-AMI
  - TRANSFER-AMI
- Facilitated STEMI
  - FINESSE

2009 Update of the STEMI and PCI Guidelines: Topics/ New Trials (2)

- Intensive Glucose Control
  - NICE-SUGAR
- Stenting
  - HORIZONS-AMI Stent
  - SYNTAX
  - SYNTAX Registry
- Fractional Flow Reserve
  - FAME
- Chronic Kidney Disease
  - CARE
- Thrombus aspiration for STEMI
  - TAPAS; thrombus aspiration for STEMI

Hospitalizations in the U.S. Due to Acute Coronary Syndromes (ACS)



Heart Disease and Stroke Statistics – 2007 Update. Circulation 2007; 115:69-171.
*Primary and secondary diagnoses. †About 0.57 million NSTEMI and 0.67 million UA.

ACC/AHA 2009 Joint STEMI/PCI Guidelines Focused Update

STEMI - Procedures

- Where (with or without surgical backup)
- Angiography
- PCI indications
- Devices choices

PCI in Hospitals Without On-Site Surgical Backup

Recommendation	COR	LOE
Primary PCI in hospitals without onsite cardiac surgery (provided that appropriate planning for program development has been accomplished)	IIa	B
Elective PCI in hospitals without onsite cardiac surgery (provided that appropriate planning for program development has been accomplished, and rigorous clinical and angiographic criteria are used for proper patient selection)	IIb	B
Primary or elective PCI in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer	III – Harm	C

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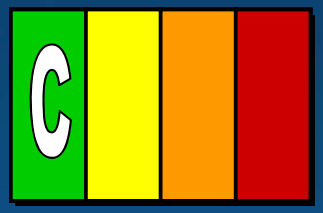
Recommendations for Triage and Transfer for PCI (for STEMI)

NEW

Recommendation

I IIa IIb III

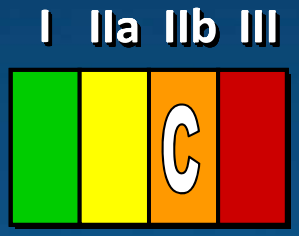


Each community should develop a STEMI system of care following the standards developed for *Mission Lifeline* including:

- Ongoing multidisciplinary team meetings with EMS, non-PCI-capable hospitals (STEMI Referral Centers), & PCI-capable hospitals (STEMI Receiving Centers)

Recommendations for Triage and Transfer for PCI (for STEMI) (cont.)

Modified Recommendation



Patients who are not high risk who receive fibrinolytic therapy as primary reperfusion therapy at a non-PCI capable facility may be considered for transfer to a PCI-capable facility as soon as possible where either PCI can be performed when needed or as a pharmacoinvasive strategy.

Coronary Angiography in STEMI

Indications	COR	LOE
Immediate coronary angiography		
Candidate for primary PCI	I	A
Severe heart failure or cardiogenic shock (if suitable revascularization candidate)	I	B
Moderate to large area of myocardium at risk and evidence of failed fibrinolysis	IIa	B
Coronary angiography 3 to 24 hours after fibrinolysis		
Hemodynamically stable patients with evidence for successful fibrinolysis	IIa	A
Coronary angiography before hospital discharge		
Stable patients	IIb	C
Coronary angiography at any time		
Patients in whom the risks of revascularization are likely to outweigh the benefits or the patient or designee does not want invasive care	III: No Benefit	C

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PCI in STEMI*

Indications	COR	LOE
Primary PCI*		
STEMI symptoms within 12 h	I	A
Severe heart failure or cardiogenic shock	I	B
Contraindications to fibrinolytic therapy with ischemic symptoms <12 h	I	B
Clinical and/or ECG evidence of ongoing ischemia between 12 and 24 h after symptom onset	IIa	B
Asymptomatic patient presenting between 12 and 24 h after symptom onset and higher risk	IIb	C
Noninfarct artery PCI at the time of primary PCI in patients without hemodynamic compromise	III: Harm	B
Delayed or Elective PCI in Patients with STEMI (i.e. Non-Primary PCI)		
Clinical evidence for fibrinolytic failure or infarct artery reocclusion	IIa	B
Patent infarct artery 3 to 24 h after fibrinolytic therapy	IIa	B
Ischemia on noninvasive testing	IIa	B
Hemodynamically significant stenosis in a patent infarct artery >24 hours after STEMI	IIb	B
Totally occluded infarct artery >24 h after STEMI in a hemodyamically stable asymptomatic patient without evidence of severe ischemia	III: No Benefit	B

*Systems goal of performing primary PCI within 90 minutes of first medical contact when the patient presents to a hospital with PCI capability **(Class I, LOE: B)**, and within 120 minutes when the patient presents to a hospital without PCI capability (**Class I, LOE: B**).

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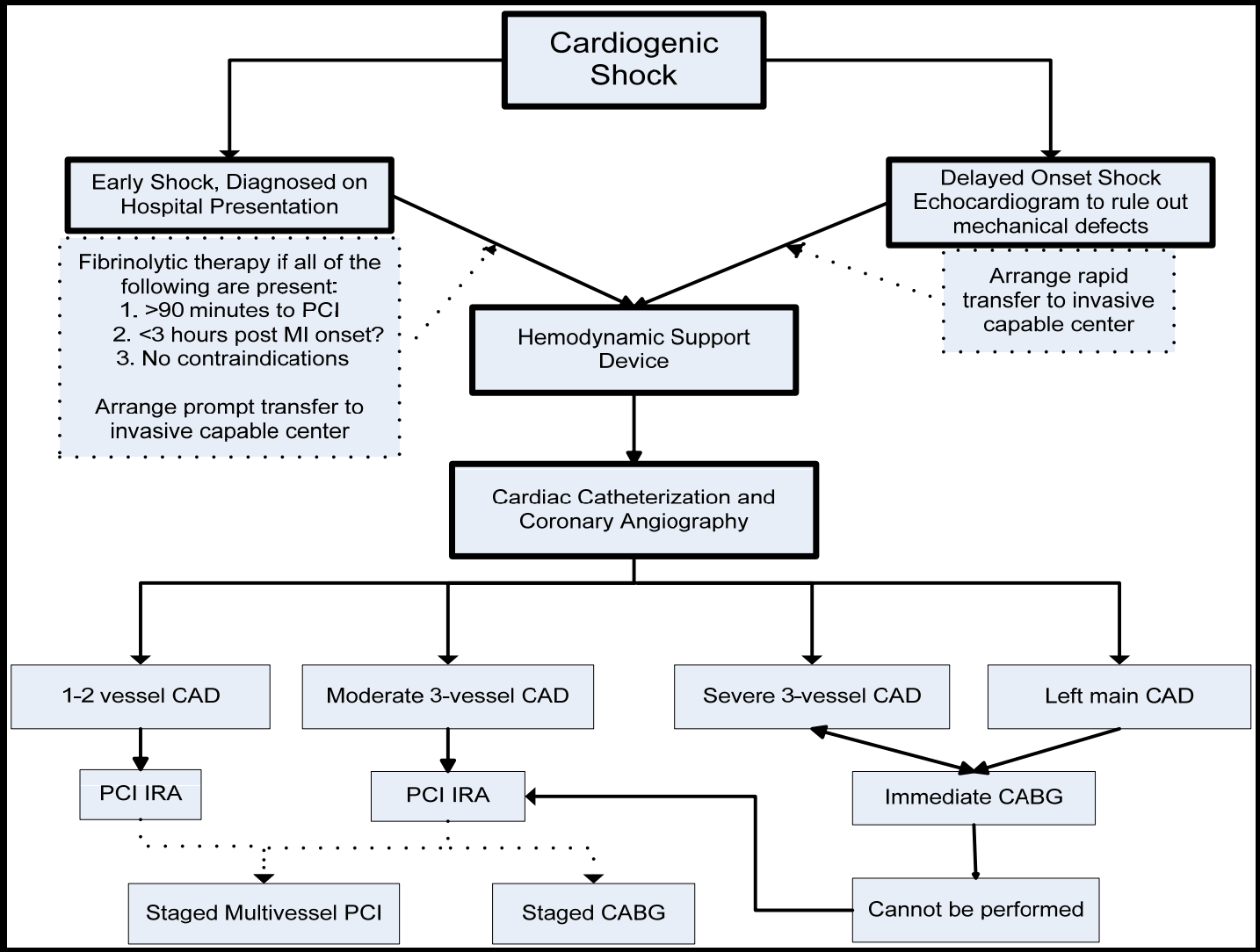
Cardiogenic Shock

Recommendation	COR	LOE
Immediate coronary angiography in patients with STEMI with severe heart failure or cardiogenic shock who are suitable candidates for revascularization	I	B
PCI for patients with acute MI who develop cardiogenic shock and are suitable candidates	I	B
Hemodynamic support device for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy	I	B

Recommendations for Initial Reperfusion Therapy When Cardiogenic Shock Complicates STEMI



Dashed lines indicate that the procedure should be performed in patients with specific indications only

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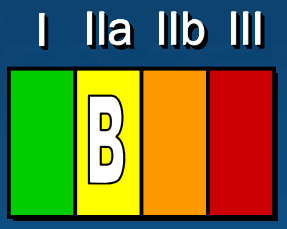
Recommendations for Thrombus Aspiration during PCI for STEMI

Thrombus Aspiration During PCI for STEMI

NEW Recommendation



Aspiration thrombectomy is reasonable for patients undergoing primary PCI

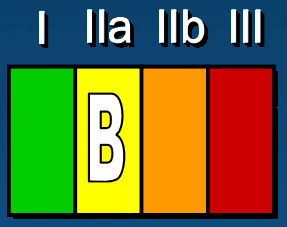
Adjunctive Therapeutic Devices

Device	Recommendation	COR	LOE
Coronary Atherectomy	Rotational atherectomy for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation	**IIa**	**C**
	Rotational atherectomy performed routinely for de novo lesions or in-stent restenosis	**III – No Benefit**	**A**
Thrombectomy	Aspiration thrombectomy for patients undergoing primary PCI	**IIa**	**B**
Laser Angioplasty	Laser angioplasty for fibrotic or moderately calcified lesions that cannot be crossed or dilated with conventional balloon angioplasty	**IIb**	**C**
	Laser angioplasty performed routinely during PCI	**III – No Benefit**	**A**
Cutting Balloon Angioplasty	Cutting balloon angioplasty to avoid slippage-induced coronary artery trauma during PCI for in-stent restenosis or for ostial lesions in side branches	**IIb**	**C**
	Cutting balloon angioplasty performed routinely during PCI	**III – No Benefit**	**A**
Embolic Protection Devices	Embolic protection devices (EPD) use during saphenous vein graft (SVG) PCI when technically feasible	**I**	**B**
Hemodynamic Support Devices	Elective insertion of an appropriate percutaneous hemodynamic support device as an adjunct to PCI in carefully selected high-risk patients	**IIb**	**C**

Recommendations for the use of stents in STEMI

Use of stents in STEMI

NEW Recommendation



It is reasonable to use a drug-eluting stent as an alternative to a bare-metal stent for primary PCI in STEMI

* Consideration for the use of stents (DES or BMS) in STEMI should include the ability of the patient to comply with prolonged dual antiplatelet therapy, the bleeding risk in patients on chronic oral anticoagulation, and the possibility that the patient may need surgery during the ensuing year

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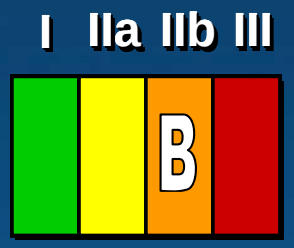
Use of stents in STEMI

MODIFIED Recommendation



A DES may be considered for clinical and anatomic settings† in which the efficacy/safety profile appears favorable

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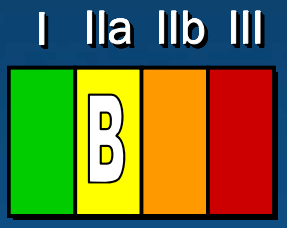
Recommendations for Intensive Glucose Control in STEMI

Intensive Glucose Control in STEMI

NEW Recommendation



It is reasonable to use an insulin based regimen to achieve and maintain glucose levels less than 180 mg/dl while avoiding hypoglycemia for patients with STEMI with either a complicated or uncomplicated course

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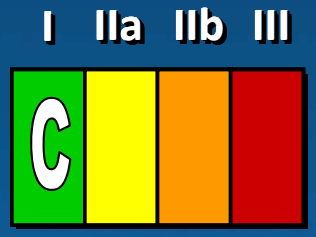
Loading doses for Thienopyridines in Patients with Acute Coronary Syndromes (STEMI and UA/NSTEMI)

Recommendations for the use of Thienopyridines

MODIFIED Recommendation

A loading dose of thienopyridine is recommended for STEMI patients for whom PCI is planned. Regimens should be one of the following:



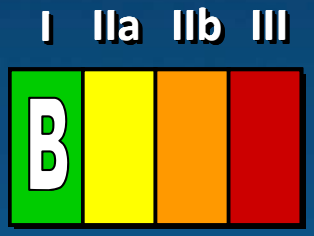
Clopidogrel at least 300 mg to 600mg† should be given as early as possible before or at the time of primary or non-primary PCI.

Recommendations for the use of Thienopyridines

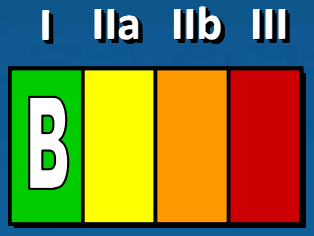
- The optimal loading dose of clopidogrel has not been established
- Randomized clinical trials using >300mg of clopidogrel as a loading dose for PCI in STEMI or UA/NSTEMI have not rigorously established superior safety or efficacy
- Clopidogrel is a prodrug which must undergo hepatic conversion to its active metabolite for platelet inhibition, a process taking several hours.

Recommendations for the use of Thienopyridines

MODIFIED Recommendation



Prasugrel 60 mg should be given as soon as possible for primary PCI.



Ticagrelor 180 mg should be given as soon as possible for primary PCI.

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Antiplatelet And Antithrombin Rx at the Time of PCI

Recommendation		COR	LOE
Oral Antiplatelet Rx			
Aspirin		I	B
$P2Y_{12}$ Inhibitor (clopidogrel*, prasugrel or ticagrelor) in patients treated with stent implantation		I	A
GP IIb/IIIa Inhibitor Rx**			
No clopidogrel pre-treatment	STEMI:	IIa	A
	UA/NSTEMI	I	A
	SIHD	IIa	B
With clopidogrel pre-treatment	STEMI	IIa	C
	UA/NSTEMI	IIa	B
	SIHD	IIb	B
Antithrombin Rx			
UFH		I	C
Bivalirudin		I	B
Enoxaparin		IIb	B
Anti-Xa Inhibitors			
Fondaparinux		III - Harm	C

*Recommended loading dose for clopidogrel is 600 mg PO

**Abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban

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GP IIb/IIIa Inhibitor Therapy*

Clopidogrel Pre-Treatment ?	Clinical Setting	COR	LOE
No	STEMI	IIa	A
	UA/NSTEMI	I	A
	SIHD	IIa	B
Yes	STEMI	IIa	C
	UA/NSTEMI	IIa	B
	SIHD	IIb	B

Additional Recommendations	COR	LOE
Administration of *intracoronary* (versus IV) abciximab administration in patients undergoing primary PCI with abciximab	IIb	B
Routine precatheterization laboratory (e.g., ambulance or	III – No	B
emergency room) administration of GP IIb/IIIa inhibitors as part of a upstream strategy for patients with STEMI undergoing PCI	Benefit	

*Recommendations apply for abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban

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No Reflow Pharmacological Therapy

Recommendation	COR	LOE
Administration of an intracoronary vasodilator (adenosine, calcium channel blocker, or nitroprusside) to treat PCI-related no-reflow that occurs during primary or elective PCI	**IIa**	**B**

$P2Y_{12}$ Inhibitor Rx Post-Stent

($P2Y_{12}$ Inhibitor = clopidogrel, prasugrel or ticagrelor)

Recommendation	COR	LOE
Post-Stent Implantation (BMS or DES) for ACS, $P2Y_{12}$ inhibitor Rx at least 12 months	I	B
Post-DES for non–ACS, clopidogrel for at least 12 mo if patients are not at high risk of bleeding.	I	B
Post-BMS for non-ACS, clopidogrel for a minimum of 1 mo and ideally up to 12 mo	I	B
Counseling patients on the importance of compliance with DAPT and to not discontinue Rx before discussion with the relevant cardiologist	I	C
Earlier discontinuation (e.g., <12 mo) of $P2Y_{12}$ inhibitor if the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation	IIa	C
Continuation of $P2Y_{12}$ Rx beyond 12 mo in patients undergoing DES placement.	IIb	C