

Dual Antiplatelet Therapy in Coronary Artery Disease
New Guidelines and Beyond

Dual Antiplatelet Therapy in **Coronary Artery Disease**

NEW GUIDELINES AND BEYOND



A CME-certified Activity

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Dual Antiplatelet Therapy in Coronary Artery Disease New Guidelines and Beyond

Disclosures

Steering Committee Disclosures

The steering committee reported the following relevant financial relationships that they or their spouse/partner have with commercial interests:

Tracy Y. Wang, MD, MHS, MSc, FACC, FAHA: *Research:* AstraZeneca, Bristol-Myers Squibb, Cryolife, Portola, Regeneron; *Consultant/Advisory Board:* AstraZeneca, Sanofi

Marlene S. Williams, MD, FACC: *Advisory Board:* Haemonetics

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Terry Ann Glauser, MD, MPH; Blair St. Amand; INCEDO: Nothing to disclose

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Educational Objectives

At the conclusion of this activity, participants should be able to:

- Apply the 2016 ACC/AHA guideline focused update on DAPT recommendations when developing individualized management plans for patients with CAD
- Consider the results of recent clinical trials investigating the optimal management of DAPT when creating management plans for patients with CAD
- Identify validated tools that can be used to individualize DAPT therapy

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Dual Antiplatelet Therapy (DAPT)

DAPT has been used to specifically refer to combination antiplatelet therapy with aspirin (ASA) and a P2Y₁₂ receptor inhibitor (clopidogrel, prasugrel, or ticagrelor)

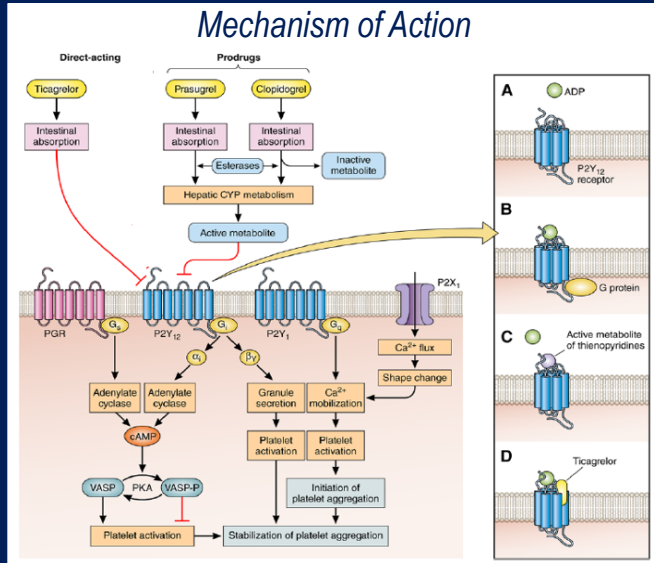
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P2Y₁₂ Inhibitors

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Oral P2Y₁₂ Inhibitors



Angiolillo DJ et al. *Circulation* 2017;136:1955-1975. Rollini F et al. *Nature Review* 2016;13:11-27. Koski R, Kennedy B. *P&T*. 2018;43:352-357.

Dosing

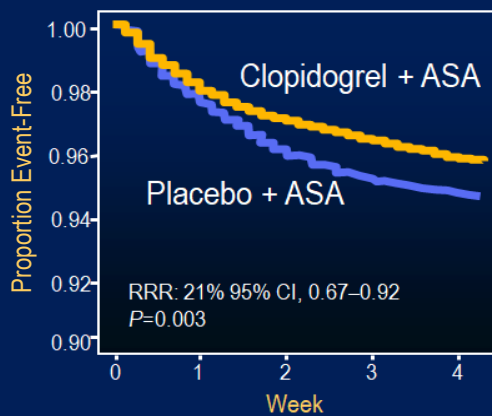
- Clopidogrel
 - Loading dose 300 mg or 600 mg
 - Maintenance dose 75 mg
- Prasugrel
 - Loading dose 60 mg
 - Maintenance dose 10 mg daily (consider 5 mg daily if weight <60 kg)
- Ticagrelor
 - Loading dose 180 mg
 - Maintenance dose 90 mg twice daily for 1 year post ACS then 60 mg twice daily

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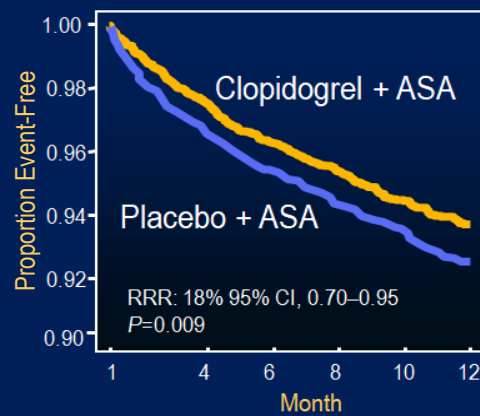
CURE: Long-term Benefit of Clopidogrel

12,562 Patients with NSTEMI-ACS, Mostly Conservatively Managed, Followed for 12 months

CV Death, MI, or Stroke, First 30 Days



CV Death, MI, or Stroke, >30 Days–1 Year



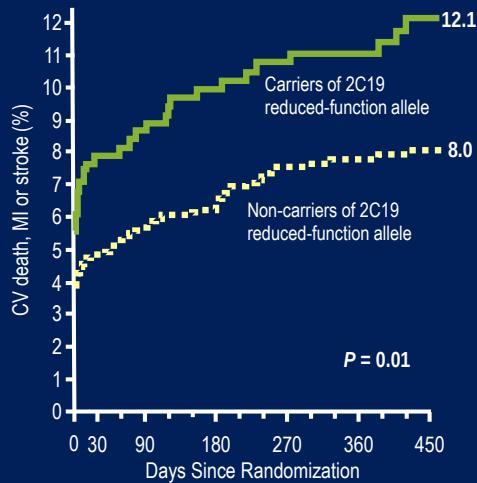
Yusuf S et al. *Circulation*. 2003;107:966-972.

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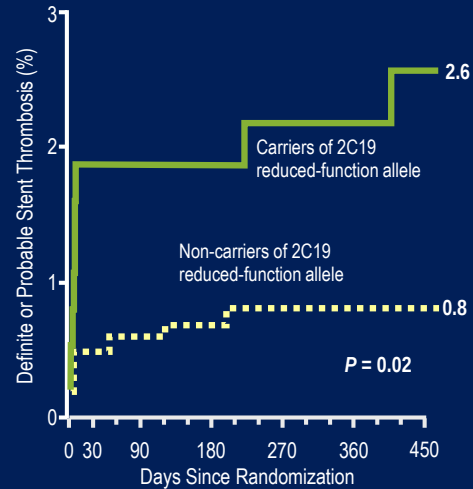
Clopidogrel: Genetic Variations and Clinical Outcomes

1^o Efficacy Outcome



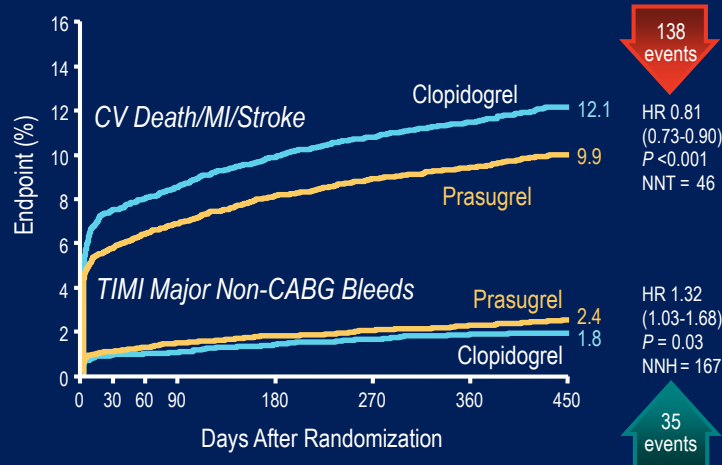
Mega JL et al. *N Engl J Med.* 2009;360:354-362.

Stent Thrombosis



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TRITON-TIMI 38: Prasugrel Efficacy and Safety



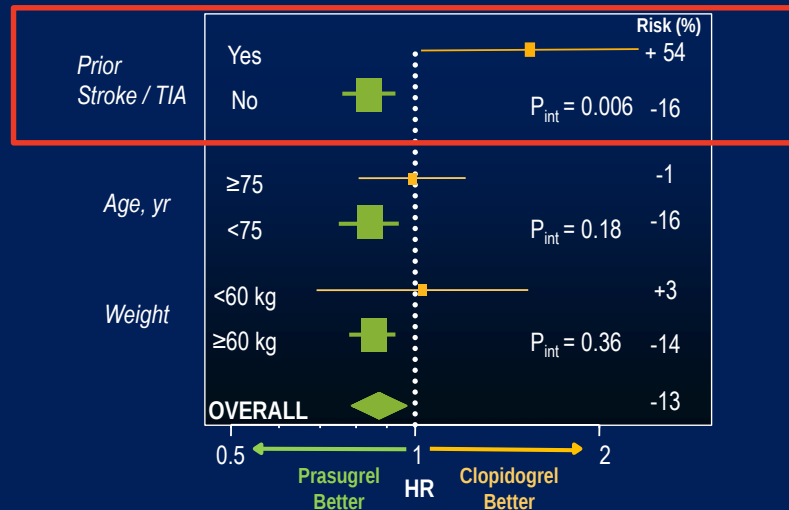
NNT = number needed to treat; NNH = number needed to harm

Wiviott SD et al. *N Engl J Med.* 2007;357:2001-2015.

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TRITON TIMI 38: Net Clinical Benefit

Prasugrel vs Clopidogrel Subgroups; Post-hoc Analysis

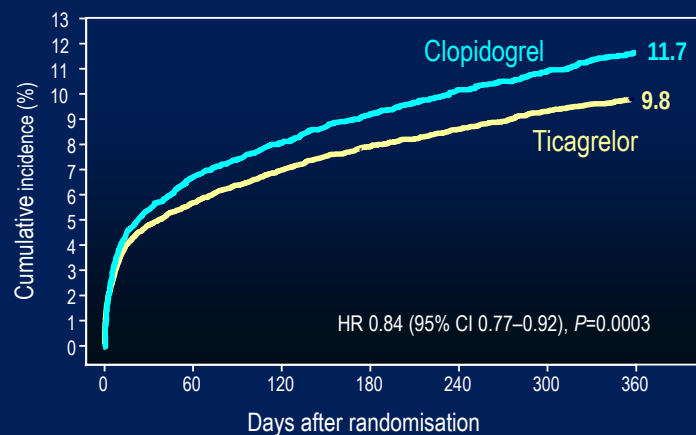


Wiviott SD et al. *N Engl J Med*. 2007;357:2001-2015.

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PLATO: Ticagrelor Efficacy

Kaplan-Meier Estimate of Time to First Primary Efficacy Event*



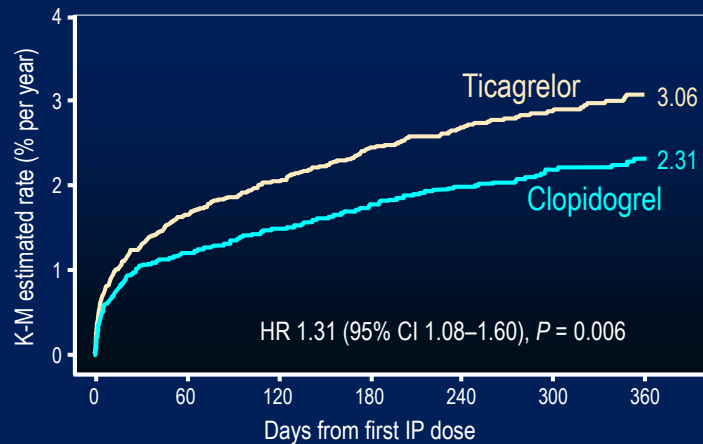
* Composite of CV Death, MI, or Stroke
Wallentin L et al. *N Engl J Med*. 2009;361:1045-1057.

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PLATO: Ticagrelor Safety

Time to Non-procedure-related Major Bleeding



Completeness of follow-up:
99.97% = 5 patients lost to follow-up

Wallentin L et al. *N Engl J Med*. 2009;361:1045-1057.

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2016 ACC/AHA Guideline

Selecting a Maintenance P2Y₁₂ Inhibitor in ACS Patients

Recommendations	COR	LOE
It is reasonable to choose ticagrelor over clopidogrel for maintenance P2Y ₁₂ treatment in ACS patients treated with an early invasive strategy and/or PCI.	Ia	B-R
It is reasonable to choose prasugrel over clopidogrel for maintenance P2Y ₁₂ treatment in ACS patients who undergo PCI who are not at high risk for bleeding complications.	Ia	B-R
Prasugrel should not be administered to patients with a prior history of stroke or TIA.	III: Harm	B-R

Levine GN et al. *J Am Coll Cardiol*. 2016;68:1082-1115

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Duration of P2Y₁₂ Inhibitor Therapy

2016 ACC/AHA Guideline *DAPT Duration after ACS*

Recommendations	COR	LOE
After ACS treated with either BMS or DES , P2Y ₁₂ inhibitor therapy should be given for at least 12 months	I	B-R
In patients with ACS treated with coronary stent implantation who have tolerated DAPT without a bleeding complication and who are not at high bleeding risk , continuation of DAPT for longer than 12 months may be reasonable	IIb	A
In patients with ACS treated with DAPT after DES implantation who develop a high risk of bleeding or develop significant overt bleeding , discontinuation of P2Y ₁₂ inhibitor therapy after 6 months may be reasonable	IIb	C

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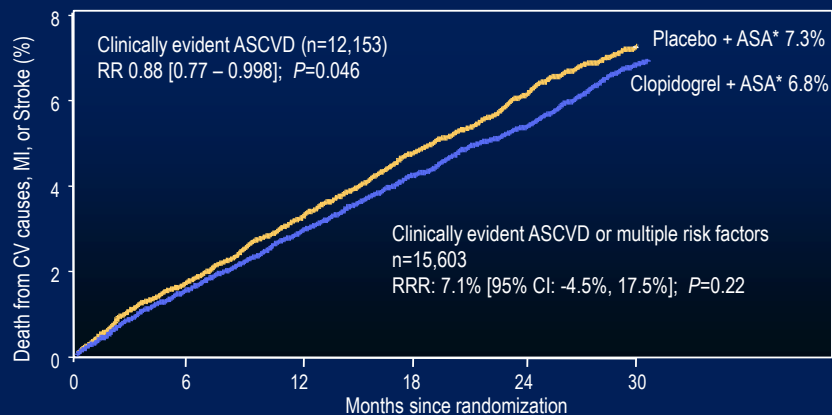
2016 ACC/AHA Guideline DAPT in Stable Ischemic Heart Disease

Recommendation	COR	LOE
In patients with SIHD treated with DAPT after BMS implantation, P2Y ₁₂ inhibitor therapy (clopidogrel) should be given for a minimum of 1 month	I	A
In patients with SIHD treated with DAPT after DES implantation, P2Y ₁₂ inhibitor therapy (clopidogrel) should be given for at least 6 months	I	B-R ^{SR}
In patients with SIHD treated with DAPT after BMS or DES, without a bleeding complication, and who are not at high bleeding risk (e.g. prior bleeding on DAPT, coagulopathy, oral anticoagulant use), continuation of DAPT with clopidogrel for longer than 1 month in patients treated with BMS or longer than 6 months in patients treated with DES may be reasonable	IIb	A ^{SR}
In patients with SIHD treated with DAPT after DES implantation who develop a high risk of bleeding (e.g. treatment with oral anticoagulant therapy), are 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 may be reasonable	IIb	C-LD
In patients with SIHD, treatment with DAPT (with clopidogrel initiated early postoperatively) for 12 months after CABG may be reasonable to improve vein graft patency	IIb	B-NR

Levine GN et al. *J Am Coll Cardiol*. 2016;68:1082-1115.

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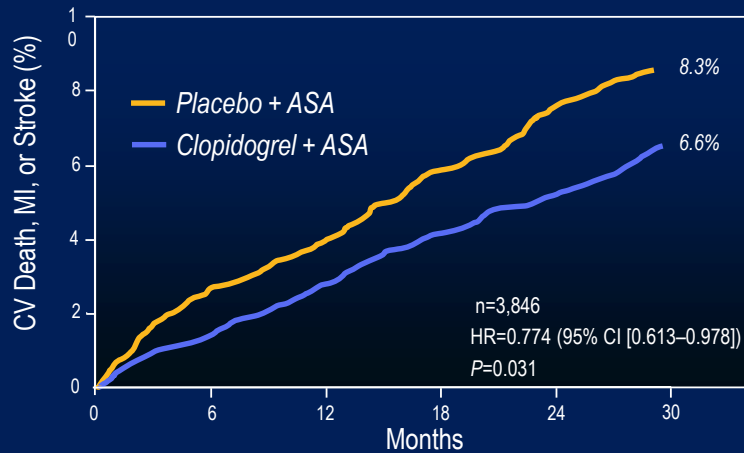
CHARISMA: Clopidogrel Plus ASA vs ASA Alone Primary Composite Endpoint for Patients Followed for a Median of 28 Months



*All patients received ASA 75-162 mg/day
Bhatt DL et al. *N Engl J Med*. 2006;354:1706-1717.

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CHARISMA: Subgroup of Patients with Prior MI Post-hoc Exploratory Analysis

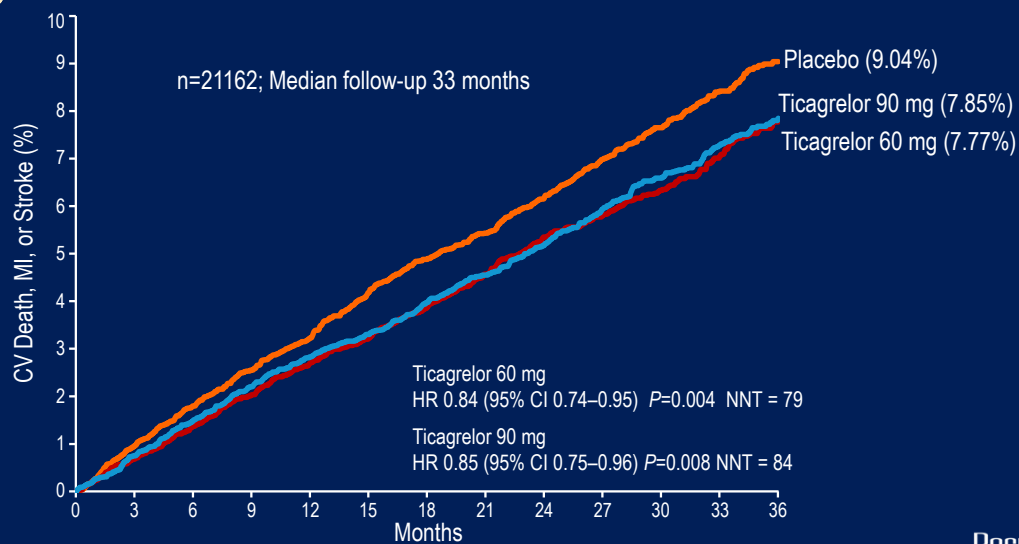


23% risk reduction for patients with prior MI

Bhatt DL et al. *J Am Coll Cardiol.* 2007;49:1982-1988.

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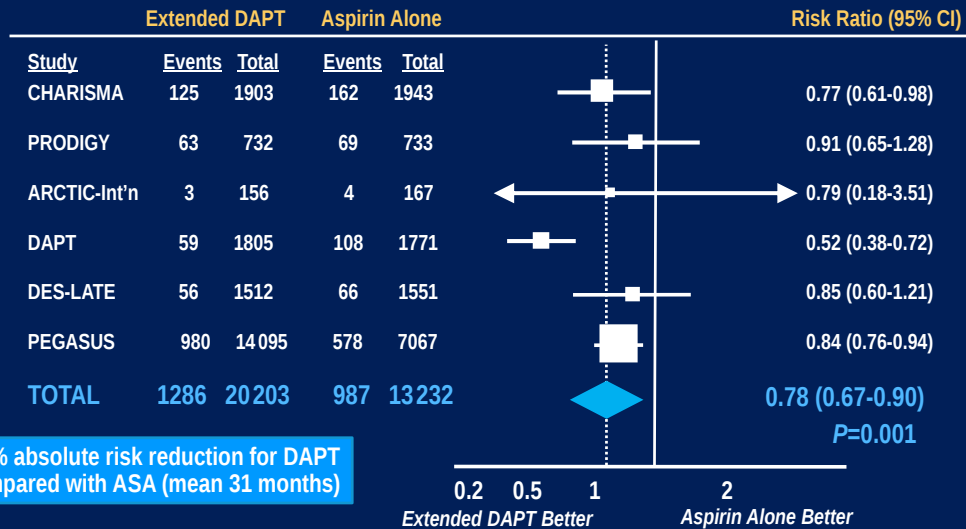
PEGASUS TIMI-54 Ticagrelor in Patients 1-3 Years Post MI



Bonaca MP et al. *N Engl J Med.* 2015;372:1791-1800.

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Meta-analysis: Extended DAPT in Prior ACS or MI Risk of CV Death/MI/Stroke

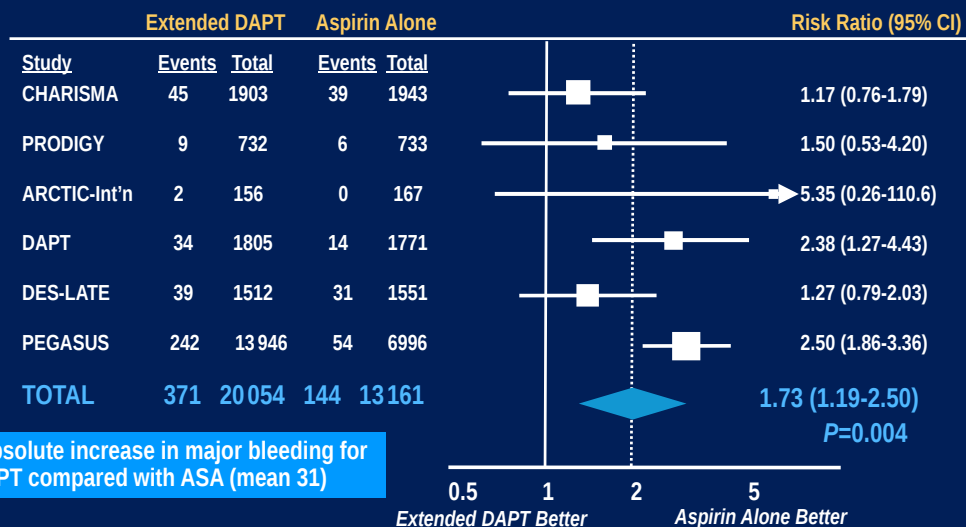


1.1% absolute risk reduction for DAPT compared with ASA (mean 31 months)

Udell JA et al. *Eur Heart J*. 2015;37:390-399.

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Meta-analysis: Extended DAPT in Prior ACS or MI Major Bleeding



0.8% absolute increase in major bleeding for DAPT compared with ASA (mean 31)

Udell JA et al. *Eur Heart J*. 2015;37:390-399.

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2016 ACC/AHA Guideline

Updated Recommendations for DAPT and Duration

- Class IIb recommendation for use beyond 12 months
- Consider ischemic risk and bleeding risk
 - Shorter duration for those with low ischemic risk and high bleeding risk
 - Longer duration for high ischemic risk and lower bleeding risk
- NSTEMI-ACS and STEMI – same recommendations
- Aspirin 81 mg should be continued indefinitely

Levine GN et al. *J Am Coll Cardiol*. 2016;68:1082-1115.

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Tools to Inform Duration of DAPT

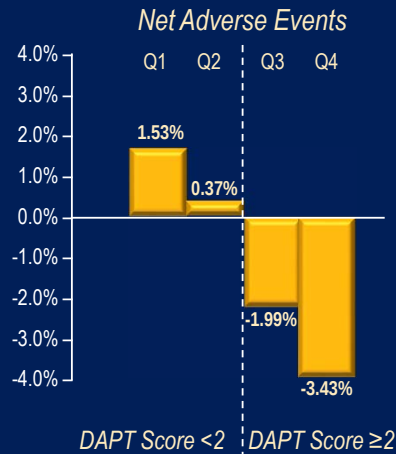
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DAPT Score and Duration of Therapy

DAPT Score

- ≥ 2 Benefit prolonged DAPT
- < 2 Shorter duration of DAPT



Clinical Prediction Score

Variable	Points
Age, y	
≥ 75	-2
65- $<$ 75	-1
$<$ 65	0
Cigarette smoking	1
Diabetes mellitus	1
MI at presentation	1
Prior PCI or prior MI	1
Paclitaxel-eluting stent	1
Stent diameter $<$ 3mm	1
CHF or LVEF $<$ 30%	2
Vein graft stent	2
Total score range: -2 to 10	

ACC DAPT Risk Calculator: tools.acc.org/DAPT/riskapp/#!/content/calculator.

Levine GN et al. *J Am Coll Cardiol*. 2016;68:1082-1115.

Yeh RW et al. *JAMA*. 2016;315:1735-1749.

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PARIS Registry Risk Score

Predicting Bleeding and Stent Thrombosis Post-DES for DAPT Duration

Risk Score for Major Bleeding

Score	Risk
0-3	Low
4-7	Intermediate
≥ 8	High

Parameter	Score
Age, years	
$<$ 50	0
50-59	+1
60-69	+2
70-79	+3
≥ 80	+4
BMI, kg/m ²	
$<$ 25	+2
25-34.9	0
≥ 35	+2
Current Smoking	
Yes	+2
No	0
Anemia	
Present	+3
Absent	0
CrCl $<$ 60 mL/min	
Present	+2
Absent	0
Triple therapy on discharge	
Yes	+2
No	0

Risk Score for Coronary Thrombosis

Score	Risk
0-2	Low
3-4	Intermediate
≥ 5	High

Parameter	Score
Diabetes mellitus	
None	0
Non-insulin dependent	+1
Insulin dependent	+3
Acute coronary syndrome	
No	0
Yes, Tn-negative	+1
Yes, Tn-positivre	+2
Current Smoking	
Yes	+1
No	0
CrCl $<$ 60 mL/min	
Present	+2
Absent	0
Prior PCI	
Yes	+2
No	0
Prior CABG	
Yes	+2
No	0

Baber U et al. *J Am Coll Cardiol*. 2016;67:2224-2234.

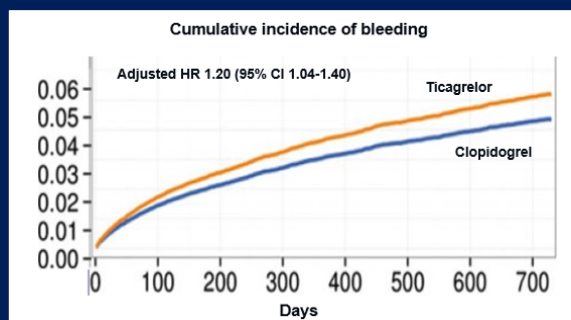
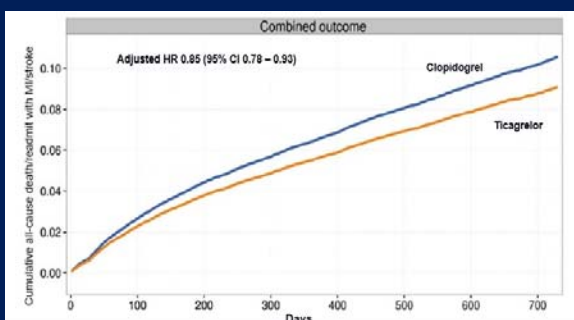
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Real-World Use of P2Y₁₂ Inhibitors in Patient Types

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SWEDHEART Registry

- Prospective cohort study
- 45,073 ACS patients discharged on ticagrelor (n = 11954) or clopidogrel (n = 33119)
 - Mean age 70 years, 70% male
 - 22.5% DM, 54.4% HTN, 24.5% current smokers, 0.5% on dialysis



Salhen A et al. *Eur Heart J.* 2016;37:3335-3342.

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US National Cardiovascular Data Registry

Ticagrelor Uptake Over Time



	PLATO Trial	NCDR	
		Ticagrelor	Clopidogrel
Mean age	62	62	65
Male	71.7	69.7	65.6
BMI	27	29.7	29.5
Diabetes	24.9	29.2	35.7
Prior MI	20.4	20.4	27.5
STEMI	37.5	56.0	36.7
Prior CABG	5.7	9.4	16.0
Discharge ASA >81 mg	0	2.5	28.2

Basra SS et al. *J Am Heart Assoc*. 2018;7:e008125.

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2016 ACC/AHA Recommendation Managing Patients Treated with Triple Therapy

- 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

Levine GN et al. *J Am Coll Cardiol*. 2016;68:1082-1115.

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2016 ACC/AHA Recommendations DAPT and PPIs

- PPI should be used if prior GI bleeding – Class I
- If risk of GI bleeding/Age/Warfarin/Steroids/NSAIDS, use of PPI reasonable – Class IIa
- NOT recommended in patients at low risk of GI bleeding – Class III

Levine GN et al. *J Am Coll Cardiol*. 2016;68:1082-1115.

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2016 ACC/AHA Recommendations For Perioperative Management

Recommendation	COR	LOE
Elective non-cardiac surgery should be delayed 30 days after BMS implantation and optimally 6 months after DES implantation	I	BR
In patients treated with DAPT after coronary stent implantation who must undergo surgical procedures that mandate the discontinuation of P2Y ₁₂ inhibitor therapy, it is recommended that aspirin be continued if possible and the P2Y ₁₂ platelet receptor inhibitor be restarted as soon as possible after surgery	I	C-EO
When non-cardiac surgery is required in patients currently taking a P2Y ₁₂ inhibitor, a consensus decision among treating clinicians as to the relative risks of surgery and discontinuation or continuation of antiplatelet therapy can be useful	IIa	C-EO
Elective non-cardiac surgery after DES implantation in patients for whom P2Y ₁₂ inhibitor therapy will need to be discontinued may be considered after 3 months if the risk of further delay of surgery is greater than the expected risks of stent thrombosis	IIb	C-EO
Elective non-cardiac surgery should not be performed within 30 days after BMS implantation or within 3 months after DES implantation in patients in whom DAPT will need to be discontinued perioperatively	III: Harm	B-NR

Levine GN et al. *J Am Coll Cardiol*. 2016;68:1082-1115.

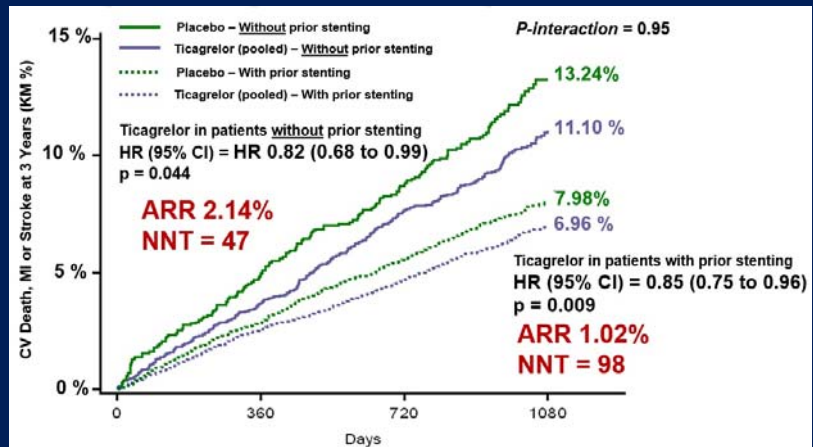
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What's New Since The Guidelines?

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PEGASUS TIMI 54 Subanalysis *Long-term Secondary Prevention*

- Post-MI patients who did not receive a stent are at elevated risk for recurrent spontaneous atherothrombosis
- Benefits of long-term DAPT are driven by decrease in events related to patient risk and not to the presence of a stent



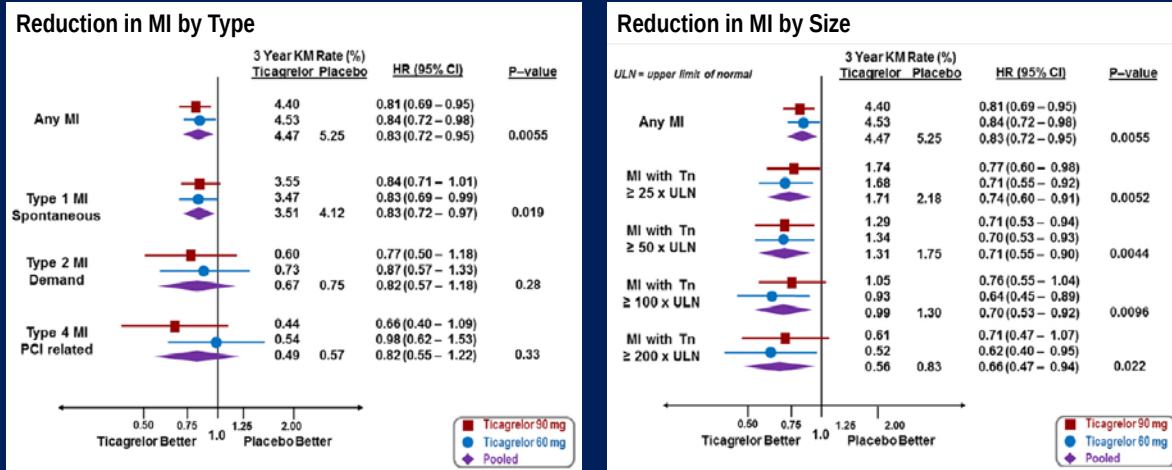
Furtado RH et al. *Circulation*. 2018;138:A14161.

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PEGASUS TIMI 54

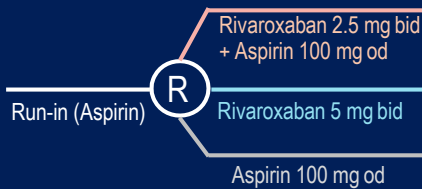
Reduction in Subtype and Size of Recurrent MI



Bonaca MP et al. *J Am Heart Assoc.* 2018;7:e009260.

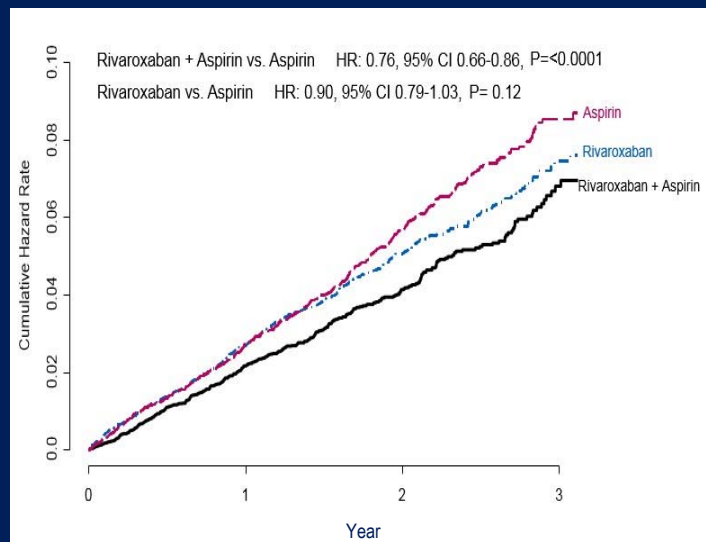
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COMPASS Trial



Stable CAD or PAD

- CAD defined as prior MI, multivessel CAD s/p PCI or CABG
- Enriched with >65 years or multiple risk factors
- Excludes patients on DAPT

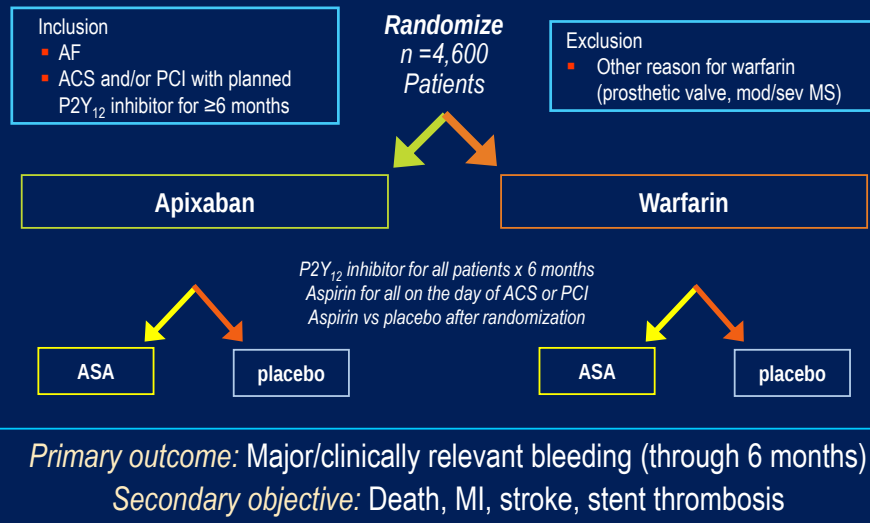


Eikelboom JW et al. *N Engl J Med.* 2017;377:1319-1330.

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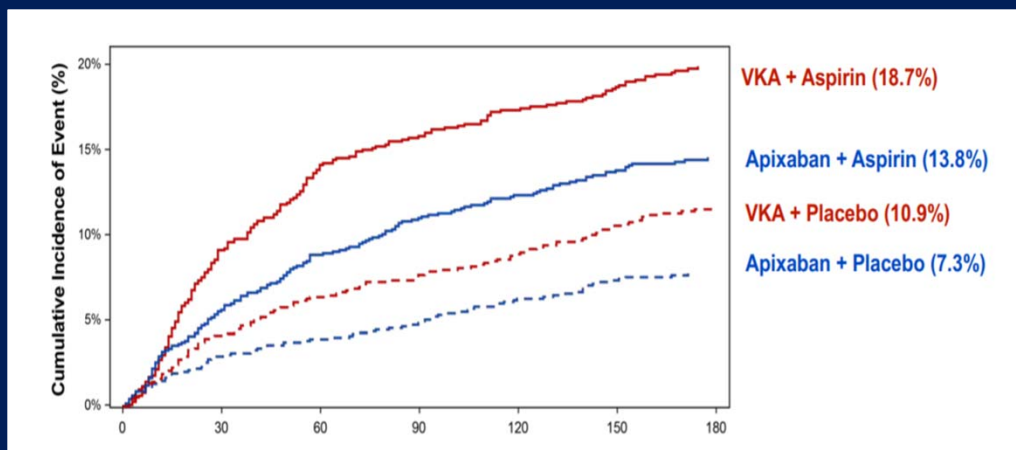
The AUGUSTUS Trial



Lopes R et al. *N Engl J Med*. 2019;380:1509-1524.

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Bleeding Outcomes Aspirin vs Placebo



Lopes R et al. *N Engl J Med*. 2019;380:1509.

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Ischemic Outcomes

Aspirin vs Placebo

Endpoint	Aspirin (N=2307)		Placebo (N=2307)	HR (95% CI)
Death / Ischemic Events (%)	6.5	→	7.3	0.89 (0.71–1.11)
Death (%)	3.1	→	3.4	0.91 (0.66–1.26)
CV Death (%)	2.3	→	2.5	0.92 (0.63–1.33)
Stroke (%)	0.9		0.8	1.06 (0.56–1.98)
Myocardial Infarction (%)	2.9	→	3.6	0.81 (0.59–1.12)
Definite or Probable Stent Thrombosis (%)	0.5	→	0.9	0.52 (0.25–1.08)
Urgent Revascularization (%)	1.6	→	2.0	0.79 (0.51–1.21)

Lopes R et al. *N Engl J Med*. 2019;380:1509.

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TWILIGHT: Ticagrelor Plus ASA vs Ticagrelor Alone

- Objective: To compare antiplatelet monotherapy with ticagrelor alone vs ticagrelor plus ASA in patients with NSTEMI-ACS undergoing PCI with DES who had completed 3 months of ticagrelor plus ASA
- Endpoints
 - Primary: Bleeding Academic Research Consortium (BARC) 2, 3, or 5 bleeding between 0 -12 months after randomization
 - Secondary: Non-fatal MI, stroke, or all-cause death between 0 -12 months after randomization
- Randomization
 - 3,555 to ticagrelor alone
 - 3,564 to ticagrelor plus ASA

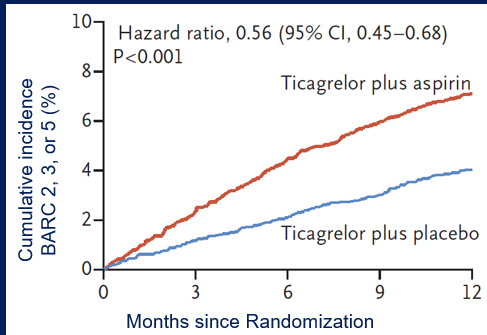
Mehran R et al. *N Engl J Med*. 2019;381:2032-2042.

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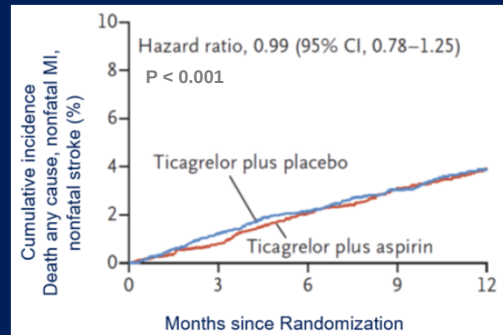
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TWILIGHT: Ticagrelor plus ASA vs Ticagrelor alone

Primary endpoint: BARC 2, 3, 5



Secondary endpoint: Any cause death, nonfatal MI, nonfatal stroke



Ticagrelor monotherapy may be a suitable antiplatelet strategy to lower bleeding risk while preserving ischemic benefit in patients who have undergone PCI. Effects appear consistent in both stable angina and ACS.

Mehran R et al. *N Engl J Med*. 2019;381:2032-2042.

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ISAR-REACT 5: Ticagrelor vs Prasugrel in ASC Patients Undergoing PCI

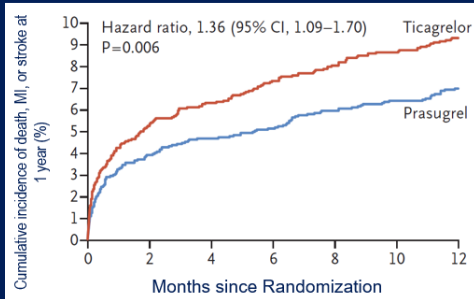
- Open label
- 2,012 randomized to ticagrelor
 - Received drug immediately after randomization
 - 32% not on assigned drug at discharge or at one year
- 2,006 randomized to prasugrel
 - STEMI patients given drug ASAP after randomization
 - In ACS not STEMI, drug not given until time of PCI (~1 hour)
 - 30% not on assigned drug at discharge or 1 year

Schupke S et al. *N Engl J Med*. 2019;381:1524-2534.

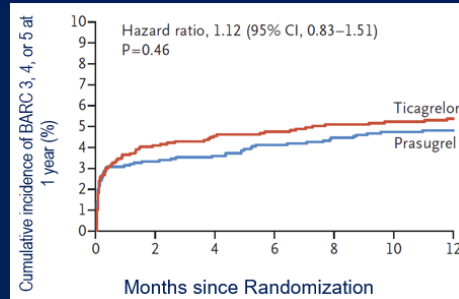
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ISAR-REACT 5: Ticagrelor vs Prasugrel in ASC Patients Undergoing PCI

Primary endpoint: Death, MI, or stroke



Secondary endpoint: BARC 3, 4, or 5



Lower incidence of death, MI, or stroke in ACS patients receiving prasugrel compared with ticagrelor.

No difference in bleeding between prasugrel and ticagrelor.

Schupke S et al. *N Engl J Med*. 2019;381:1524-1534.

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Switching P2Y₁₂ Inhibitors

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P2Y₁₂ Inhibitor Switching

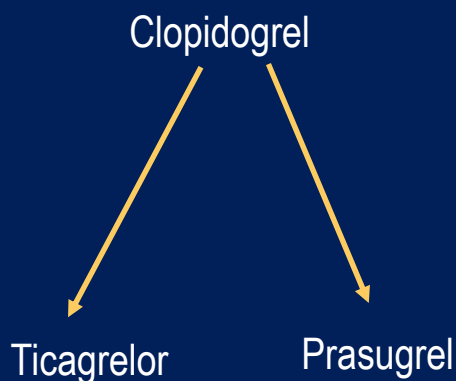
7.6% of 8,672 MI Patients Switched within 1-year Post Discharge

	Clopidogrel	Ticagrelor	Prasugrel
Post-discharge switch	3.6%	28.3%	15.4%
Days to switch	21	62	80
<i>Patient-reported reason for switch</i>			
Bleeding*	6.9%	10.9%	13.1%
Other side effect	31.9%	18.8%	10.2%
Cost	7.9%	43.6%	39.1%
<i>Event triggering switch</i>			
MI/stroke/unplanned revasc	18.5%	1.8%	2.1%
Bleeding*	0.9%	1.6%	1.3%

Zettler MJ. Am Heart J. 2017;183:62-68.

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P2Y₁₂ Inhibitor Escalation



Acute Phase

- Loading dose anytime after last clopidogrel dose
 - Prasugrel 60 mg
 - Ticagrelor 180 mg
- Maintenance dose prasugrel 10 mg OR ticagrelor 90 mg twice daily

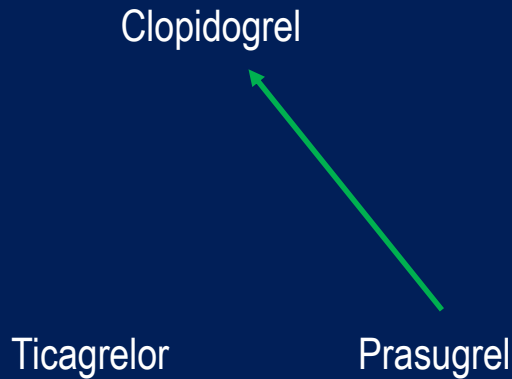
Non-Acute Phase

- No loading dose either agent
- Maintenance dose 24 hours after last clopidogrel dose
- Timing similar for elderly or low-body-weight patients using prasugrel 5 mg

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P2Y₁₂ Inhibitor De-escalation

Prasugrel to Clopidogrel



Acute Phase

- 600 mg loading dose 24 hours after last prasugrel dose then maintenance
- No loading if bleeding

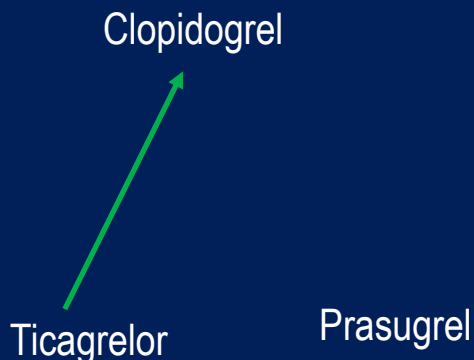
Non-Acute Phase

- No loading dose
- Clopidogrel 75 mg (maintenance dose) 24 hours after last prasugrel dose

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P2Y₁₂ Inhibitor De-escalation

Ticagrelor to Clopidogrel



Acute Phase

- 600 mg loading dose of clopidogrel 24 hours after last ticagrelor dose

Non-Acute Phase

- 600 mg loading dose of clopidogrel 24 hours after last ticagrelor dose
- No loading if bleeding; use maintenance dose only

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Change Between Higher Potency P2Y₁₂ Inhibitors

Acute and Non-Acute Phases

60 mg loading dose prasugrel 24 hours after last ticagrelor dose

Ticagrelor

Prasugrel

Non-Acute Phase

- No ticagrelor loading dose needed
- Start 90 mg ticagrelor 24 hours after last prasugrel dose then maintenance 90 mg ticagrelor twice daily

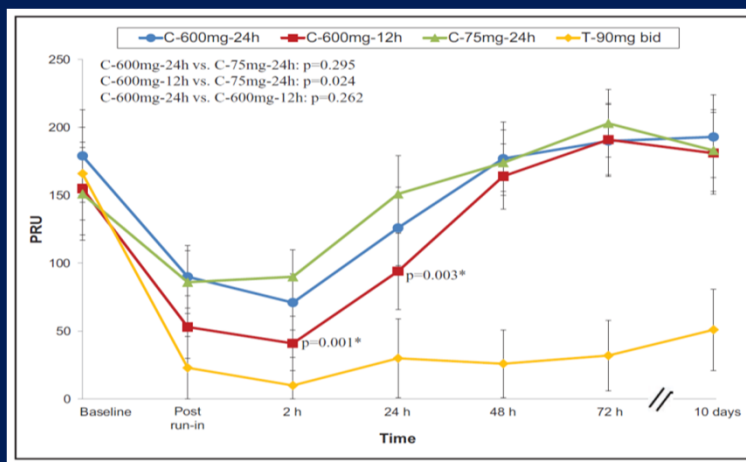
Acute Phase

Can consider loading dose 24 hours after last prasugrel dose

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SWAP-4 Results

Switching from Ticagrelor to Clopidogrel



- De-escalation from ticagrelor to clopidogrel therapy is associated with increased platelet reactivity
- The use of a loading dose before a maintenance dose mitigates this increased platelet reactivity

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Communicating with Patients for Optimal Results

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Being a Part of the Team *The Patient Perspective*



Patients want:

1. All of their options explained in language they can understand
2. To be a part of the team
3. To be listened to and understood
4. To be given time to absorb the information before making a critical decision
5. To have a trustworthy place to find information



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Dual Antiplatelet Therapy in Coronary Artery Disease New Guidelines and Beyond

How You Can Help

1. Don't use acronyms or medical jargon. Explain the diagnosis and/or options in simple terms.
2. Talk with the patient in a back-and-forth dialogue. Ask questions to determine their level of understanding.
3. Remember that this may be routine to you, but this can be a life-changing moment for the patient.
4. For a critical diagnosis or major decision, consider giving the patient time and follow-up (either in person or via telephone) to assure they understand what is happening.
5. Provide your patients with websites (they are going to Google anyway) that are filled with good information.
6. Consider their emotional needs: Connect them with support services or support groups in your hospital.



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Educational Resources

Mended Hearts
www.mendedhearts.org
1-888-HEART-99

Heart Guides



Go-To Guides



Discussion Guides



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Summary DAPT Recommendations

- DAPT should be continued for one month in SIHD with BMS and six months with DES
- DAPT should be continued for twelve months in ACS (sp PCI/CABG/medical management)
- ASA dosing should be 81 mg (75-100 mg) with DAPT
- Elective non-cardiac surgery should not be performed within 30 days after BMS or 3 months after DES (Class III)

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Summary DAPT Recommendations (2)

- Real-world studies show the benefit of ticagrelor over clopidogrel in reduction of ischemic events; however, bleeding events are increased
- De-escalation from ticagrelor to clopidogrel requires a loading dose of clopidogrel
- Extended duration DAPT should be considered based on ischemic and bleeding risks, risk scores (e.g. DAPT score) help in decision-making

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Dual Antiplatelet Therapy in Coronary Artery Disease
New Guidelines and Beyond

Dual Antiplatelet Therapy in Coronary Artery Disease

NEW GUIDELINES AND BEYOND



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