

# **NHỮNG THẮNG ĐIỂM ĐÁNH GIÁ NGUY CƠ XUẤT HUYẾT KHÁNG KẾT TẬP TIỂU CẦU KÉP (DAPT) Ở BỆNH NHÂN BỆNH ĐỘNG MẠCH VÀNH**

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*PGĐ BV Thống Nhất, TPHCM*

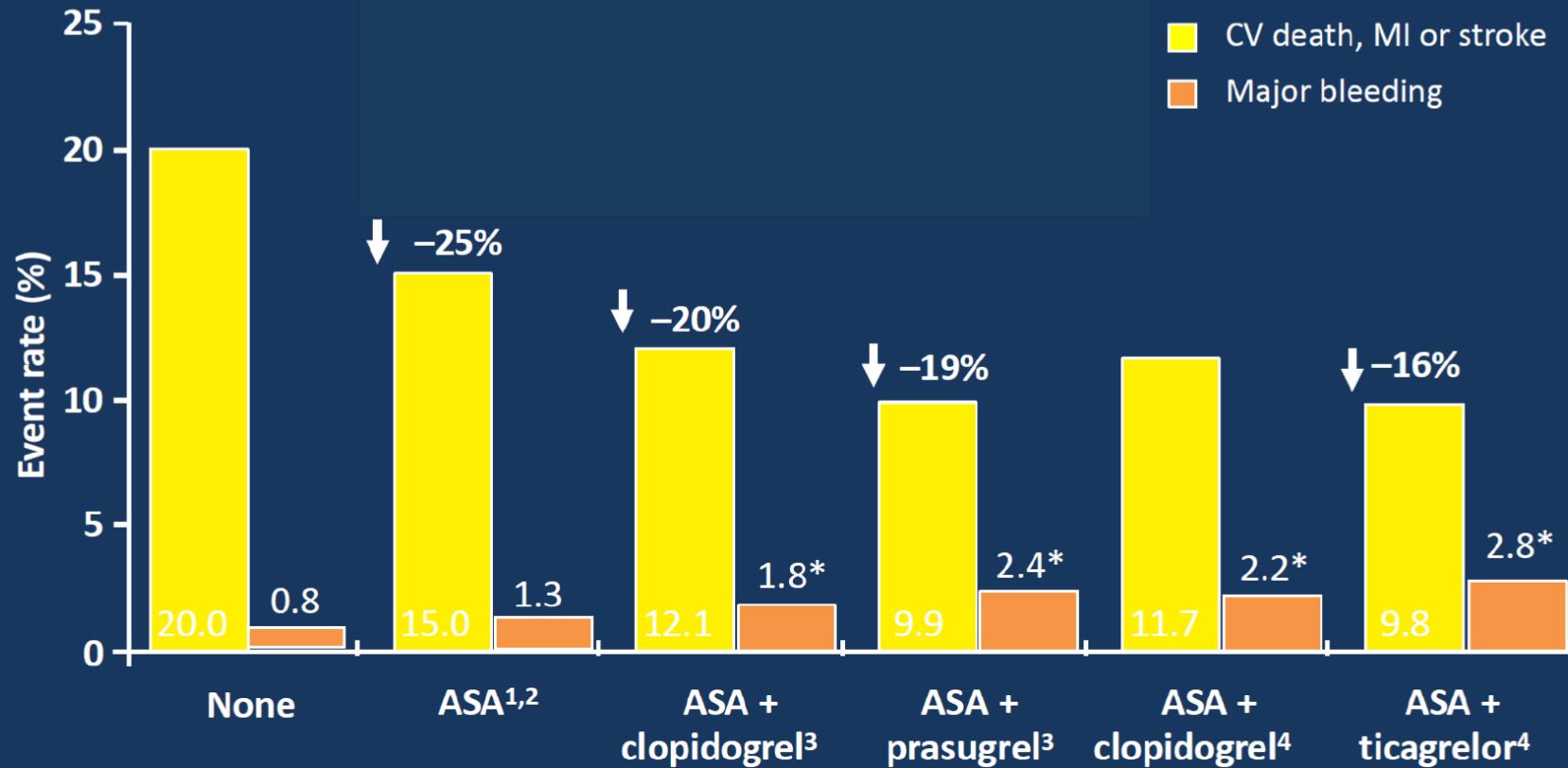
*PCT Hội Tim mạch Can thiệp Việt Nam*

**TP HCM, 11/ 2019**

# Sử dụng DAPT nghệ thuật cân bằng Huyết khối- Xuất huyết

Delicate balance between **thrombus** and **bleeding**, after 12 months

PGS TS Hồ Thượng Dũng, TPHCM, VN



\*Major bleeding: non-CABG-related TIMI major bleeding

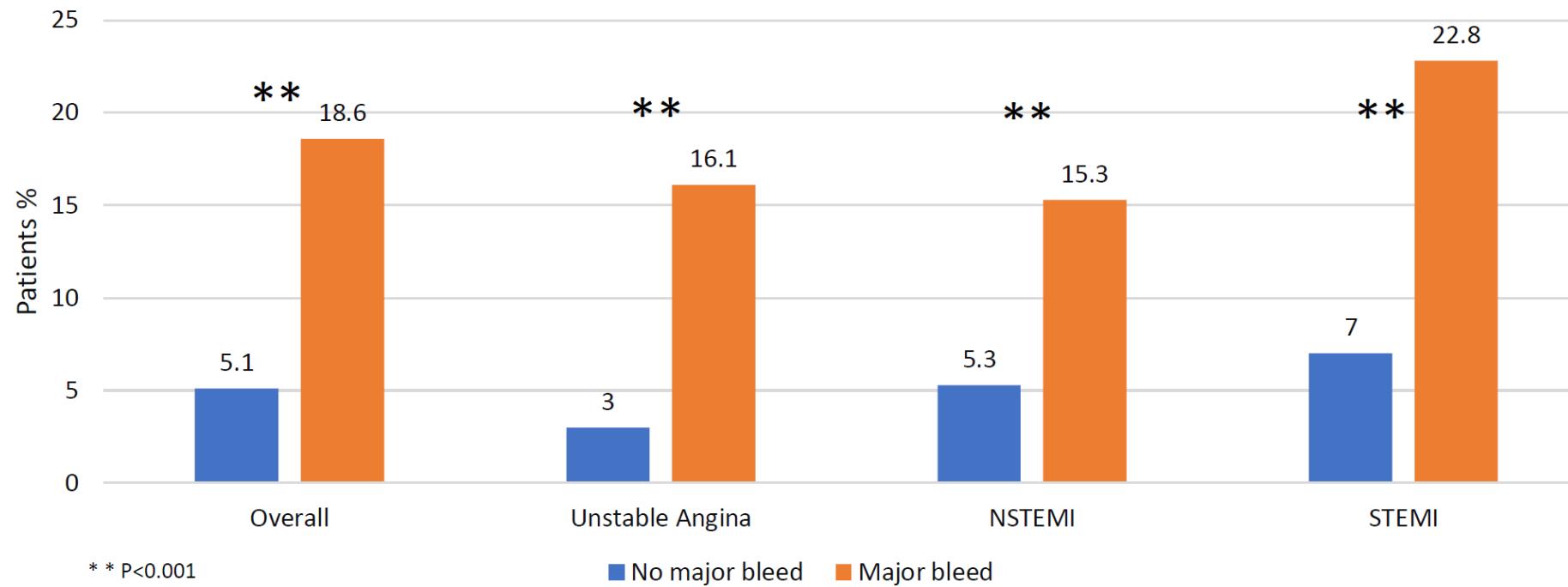
1. Antiplatelet Trialists' Collaboration, 1994; 2. Antithrombotic Trialists' Collaboration, 2002; 3. Wiviott *et al.* 2007; 4. Wallentin *et al.*, 2009

# **BIỄN CHỨNG XUẤT HUYẾT KẾT CỤC VÀ DỰ HẬU**

# XUẤT HUYẾT LÀM TĂNG NGUY CƠ TỬ VONG NỘI VIỆN TRONG HỘI CHỨNG VÀNH CẤP

Tỉ lệ tử vong nội viện liên quan biến cố xuất huyết nặng trên 24,045 BN HCVC - GRACE

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# XUẤT HUYẾT LÀM TĂNG TỈ LỆ TỬ VONG TRONG 6 THÁNG Ở BỆNH NHÂN UA/NSTEMI

26.450 BN ACS từ nghiên cứu GUSTO IIb, PURSUIT và PARAGON A&B

Outcome	Degree of Bleeding			
	None	Mild	Moderate	Severe
<b>Unadjusted rates (%)</b>				
30-d end points				
Death <sup>†</sup>	549/19,110 (2.9%)	155/4,387 (3.5%)	154/2,599 (5.9%)	79/307 (25.7%)
MI <sup>†</sup>	1,412/19,110 (7.4%)	501/4,373 (11.5%)	605/2,591 (23.4%)	100/306 (32.7%)
Death or MI <sup>†</sup>	1,758/19,110 (9.3%)	572/4,372 (13.1%)	675/2,591 (26.1%)	151/306 (49.4%)
6-mo end point				
Death <sup>†</sup>	983/18,886 (5.2%)	273/4,358 (6.3%)	253/2,566 (9.9%)	107/305 (35.1%)
<b>Adjusted hazard ratios (95% confidence intervals)</b>				
30-d end points				
Death	1.0 <sup>‡</sup>	1.6 (1.3–1.9)	2.7 (2.3–3.4)	10.6 (8.3–13.6)
Death or MI	1.0 <sup>‡</sup>	1.3 (1.2–1.5)	3.3 (2.9–3.7)	5.6 (4.6–6.8)
6-mo end point				
Death	1.0 <sup>‡</sup>	1.4 (1.2–1.6)	2.1 (1.8–2.4)	7.5 (6.1–9.3)

\* Hazard ratios were adjusted for age, gender, body weight, site of randomization, diabetes mellitus, smoking status, peripheral vascular disease, chest pain duration, Killip's class, MI at enrollment, heart rate, prerandomization medications, systolic blood pressure, and treatment assignment (active vs control).

<sup>†</sup> p <0.001.

<sup>‡</sup> Reference.

# Bleeding-Related Deaths in Relation to the Duration of Dual-Antiplatelet Therapy After Coronary Stenting

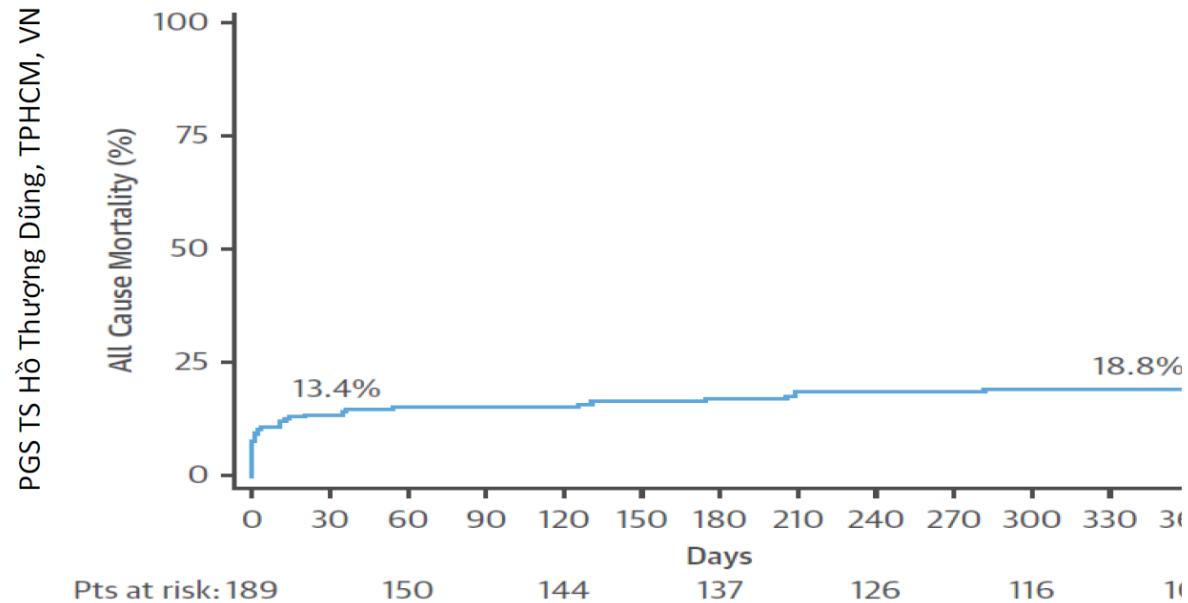


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**12 randomized studies with 34880 patients**

**IPD for 6 randomized studies with 11473 patients**

# Bleeding and mortality



Before or not bleeding

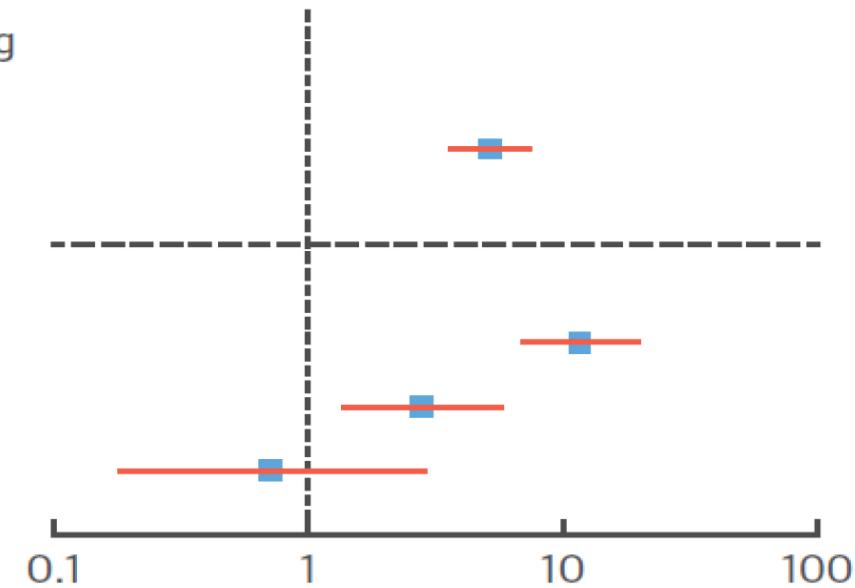
After bleeding

Days

0-30

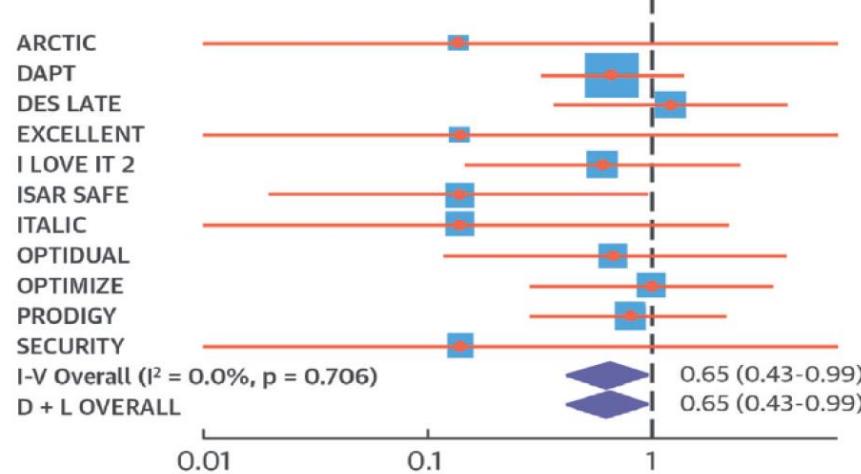
31-365

>365

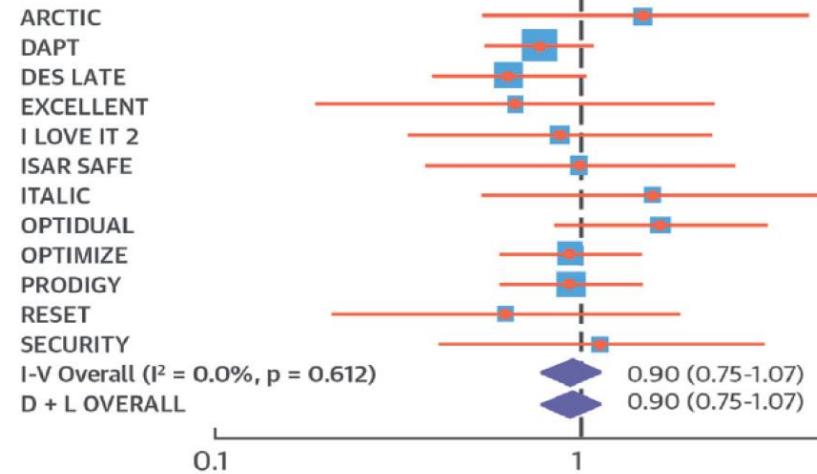


# Mechanistic link between DAPT bleeding and mortality

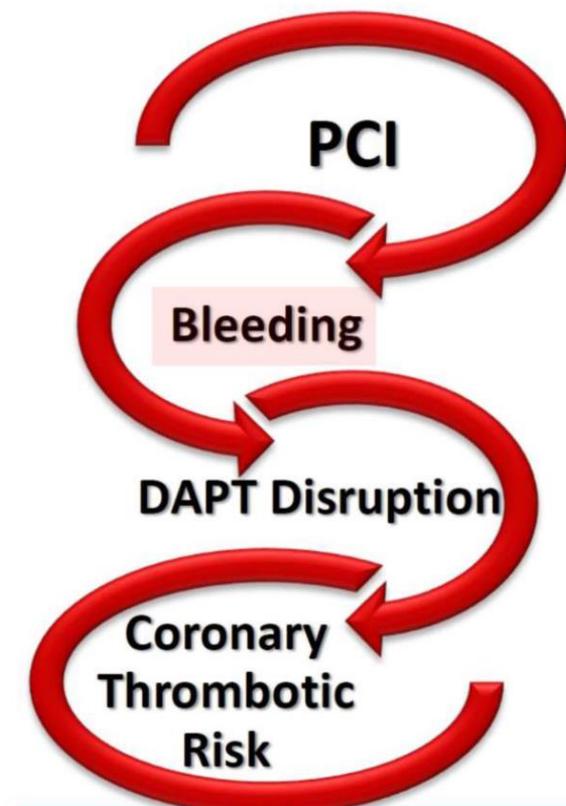
A. Bleeding-related Deaths



B. Non-Bleeding-related Deaths



Palmerini, T. et al. J Am Coll Cardiol. 2017;69(16):2011-22.



*Life is Matter of Balance!*



# *Life is Matter of Balance!*

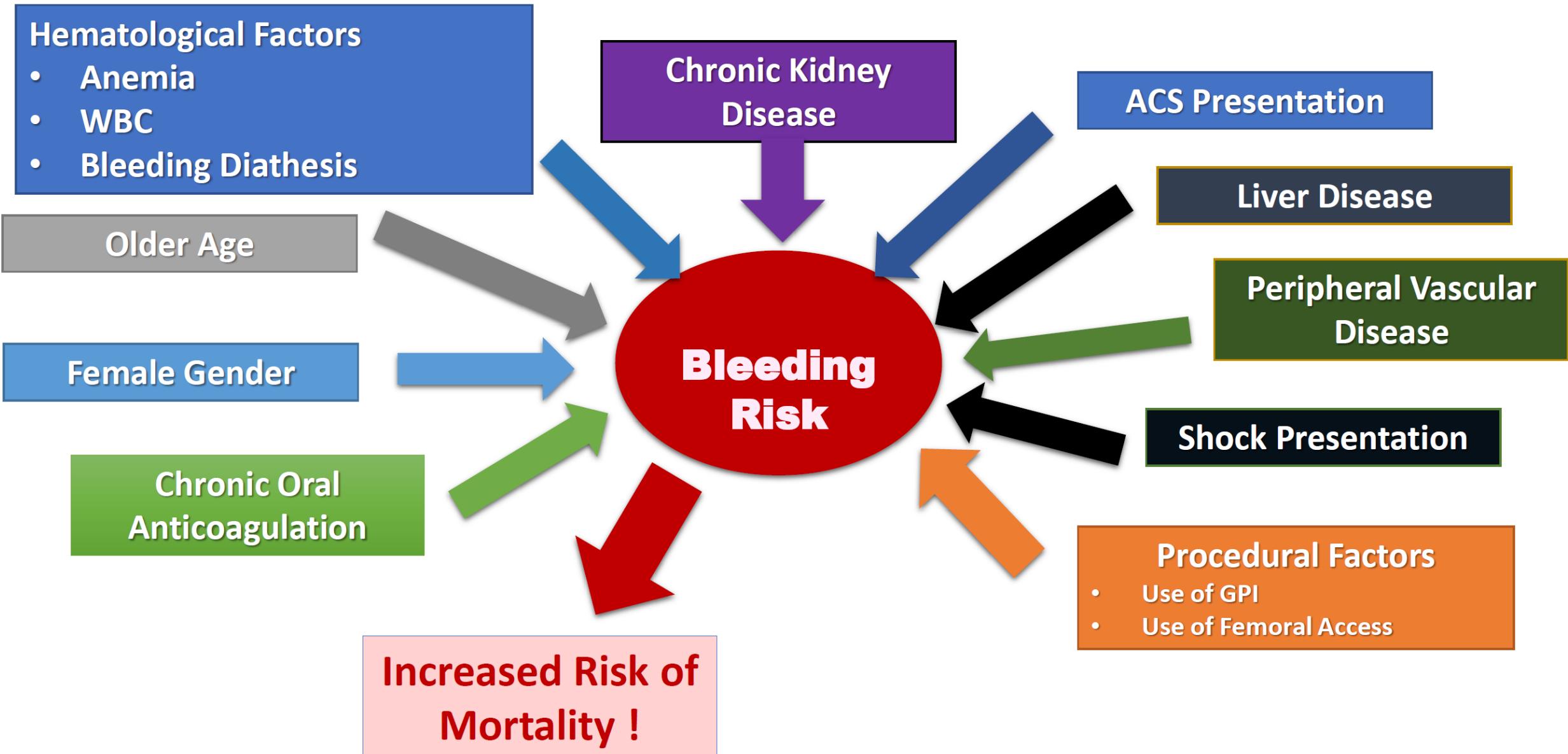
*...more complicated...*



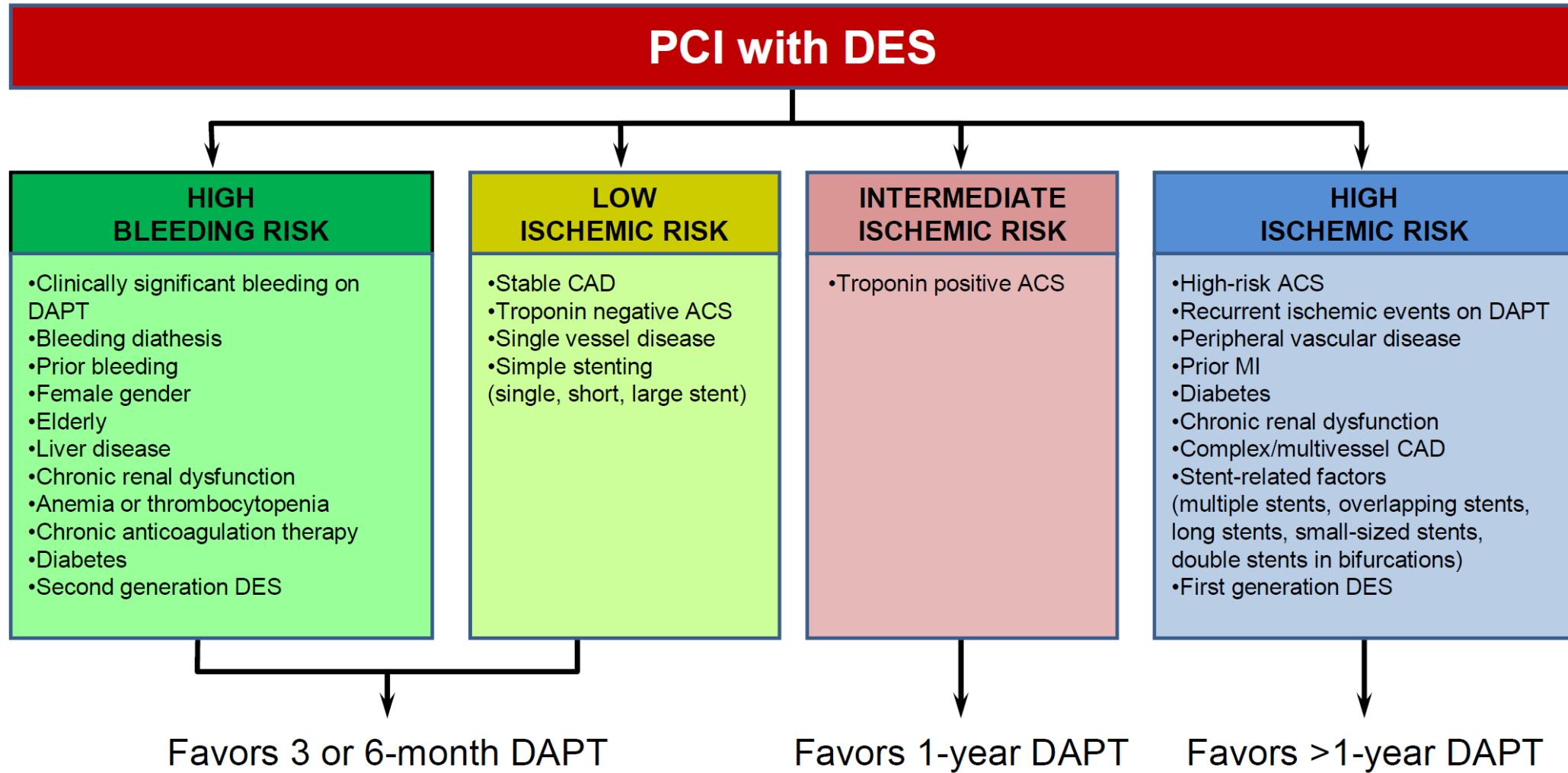
CÁ THỂ HÓA LIỆU PHÁP DAPT  
*hay*

**CHIẾN LƯỢC CÂN BẰNG**  
*lợi ích và nguy cơ*

# Bleeding Risk: A Comprehensive Clinical Assessment



# DAPT Duration: Factors to be weighed



When assessing ischemic risk, clinical presentation (ACS vs stable CAD) and disease/PCI complexity are two of the most important factors to consider

# Các đặc tính làm tăng nguy cơ biến cố huyết khối khi đặt stent mạch vành

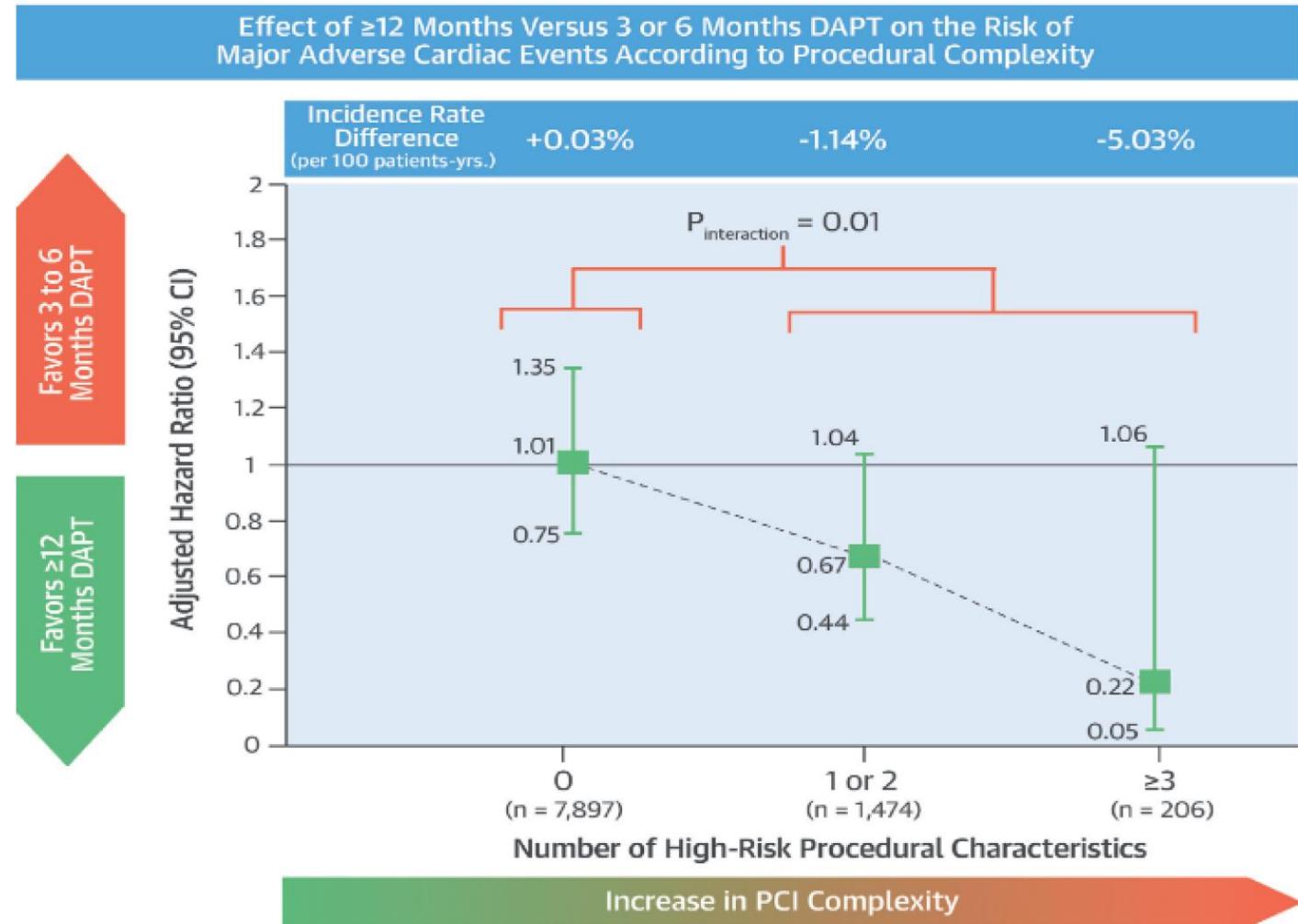
- Prior stent thrombosis on adequate antiplatelet therapy.
- Stenting of the last remaining patent coronary artery.
- Diffuse multivessel disease especially in diabetic patients.
- Chronic kidney disease (i.e. creatinine clearance <60 mL/min).
- At least three stents implanted.
- At least three lesions treated.
- Bifurcation with two stents implanted.
- Total stent length >60 mm.
- Treatment of a chronic total occlusion.

# Does PCI Complexity Favor Longer-Term DAPT?

Pooled analysis of 6 RCTs  
comparing 3-6 months DAPT  
vs.  $\geq$  12 months DAPT

## Complex Features:

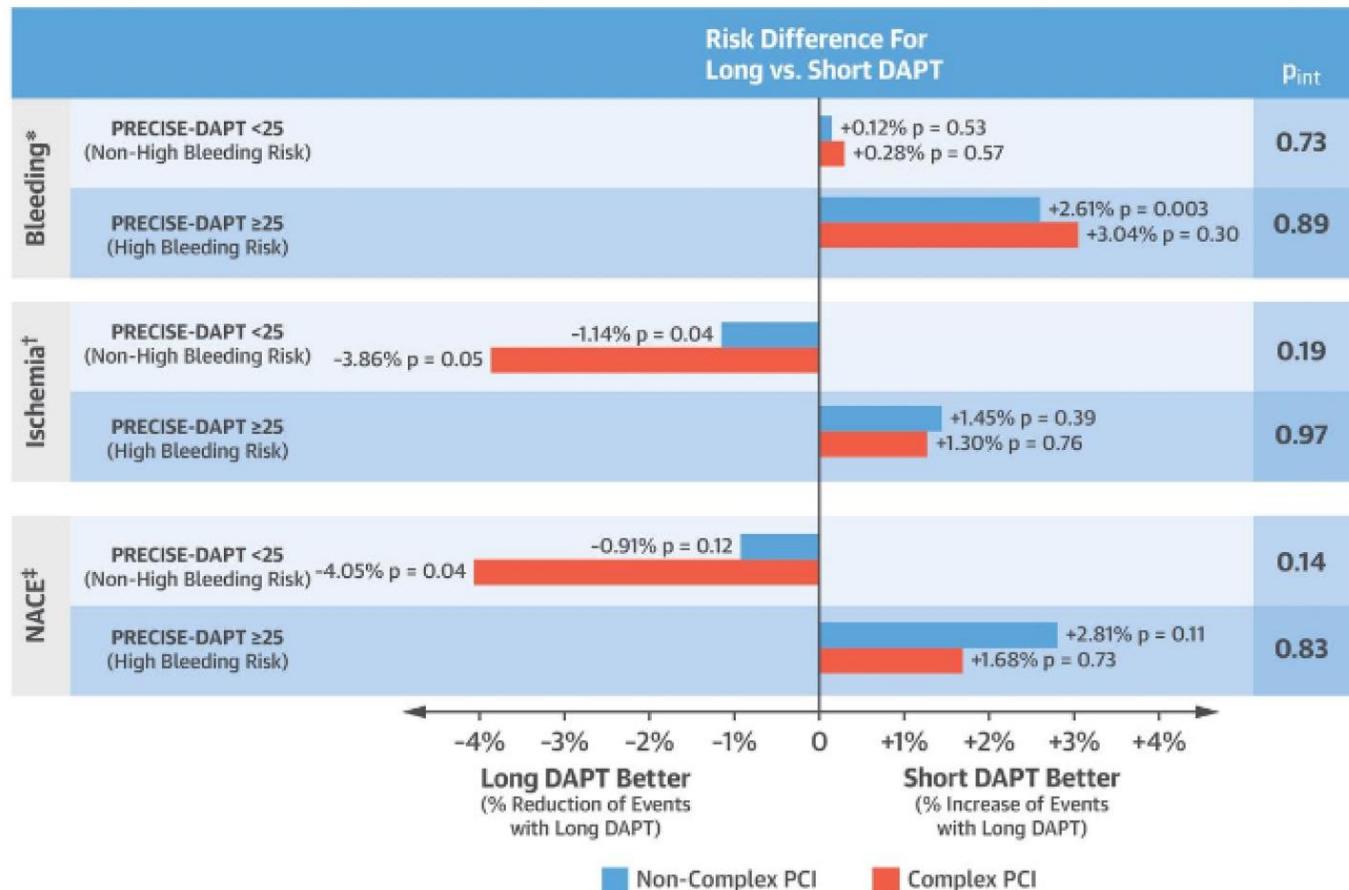
- 3 vessels treated
- $\geq$  3 stents placed
- $\geq$  3 lesions treated
- Bifurcation with 2 stents
- Total stent length  $>$  60 mm
- CTO



Giustino, G. et al. J Am Coll Cardiol. 2016;68(17):1851-64.

# Coronary Complexity in HBR Patients

## CENTRAL ILLUSTRATION: PRECISE-DAPT Score and Complex Percutaneous Coronary Intervention



Costa, F. et al. J Am Coll Cardiol. 2019;73(7):741-54.

HBR Patients did NOT benefit from longer duration of DAPT irrespective of lesion complexity

# Tailoring DAPT duration: summary of the evidence

- Clinical presentation
- Complexity of CAD
- Diabetes
- CKD
- Age

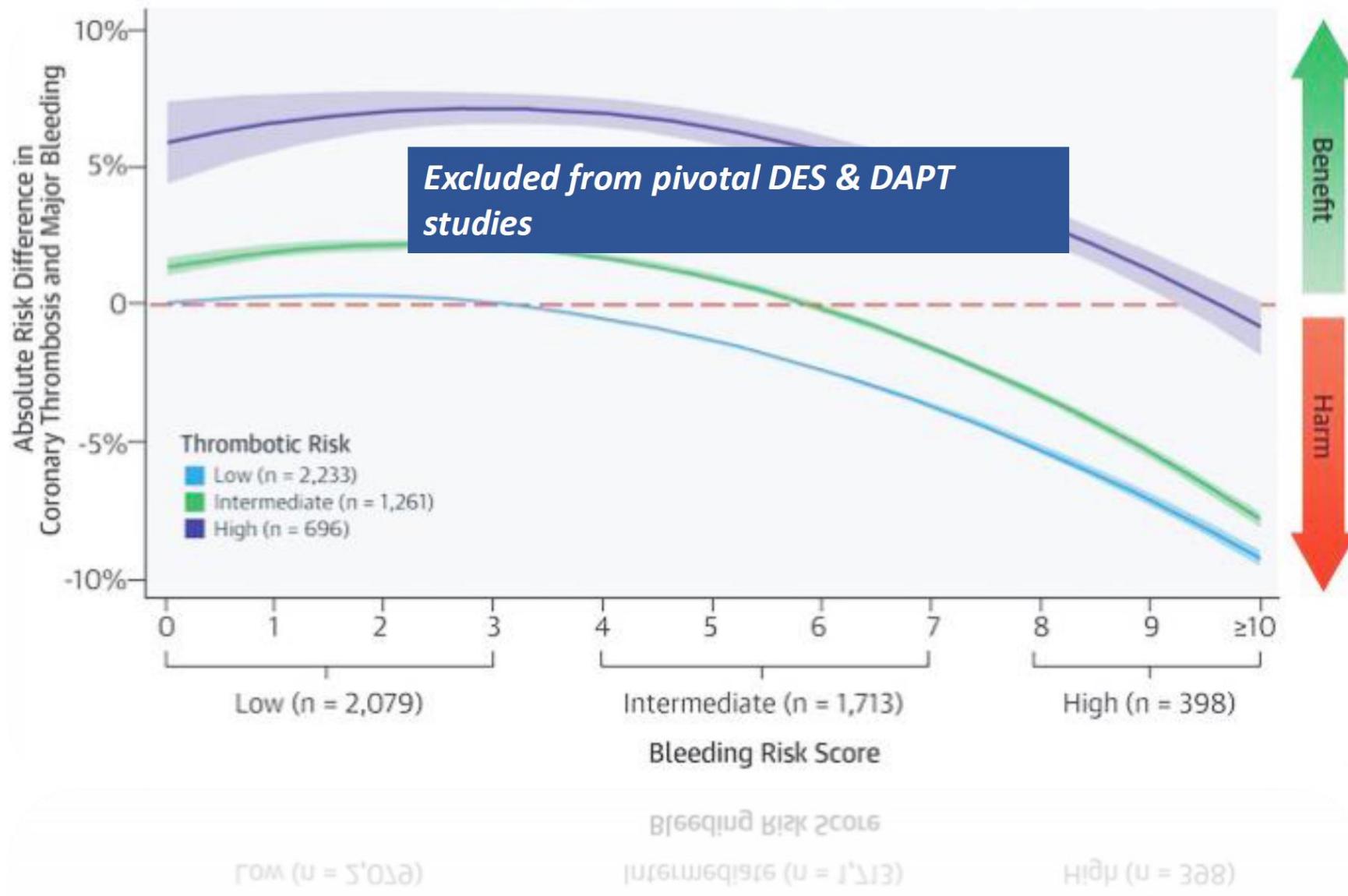
# CÁC THANG ĐIỂM ĐÁNH GIÁ NGUY CƠ XUẤT HUYẾT Ở BỆNH NHÂN **SỬ DỤNG DAPT**

# Risk Scores for DAPT Duration

Score	Number of variables	Development cohort (patients, design)	Setting	Predicted outcome(s)	Validation cohort(s) (patients, c-index)
DAPT	5 clinical, 3 procedural	N=11,648, multicentre randomized clinical trial	PCI patients on DAPT who were event-free for 12 months	Ischemia and bleeding between 12 and 30 months after PCI	N=8,136, 0.64 for both ischemia and bleeding
PARIS	Coronary thrombosis risk score: 6 clinical  Major bleeding risk score: 6 clinical	N=4,190 patients, multicentre registry	PCI patients on DAPT	Ischemia and bleeding at 24 months after PCI	N=8,665, 0.65 for ischemia and 0.64 for bleeding
PRECISE-DAPT	5 clinical	N=14,963, pooled analysis of randomized clinical trials	PCI patients on DAPT	Bleeding at 12 months after PCI	N=8,595, 0.70 N=6,172, 0.66

•Capodanno D, Angiolillo DJ. Lancet 2017; 389: 987-9

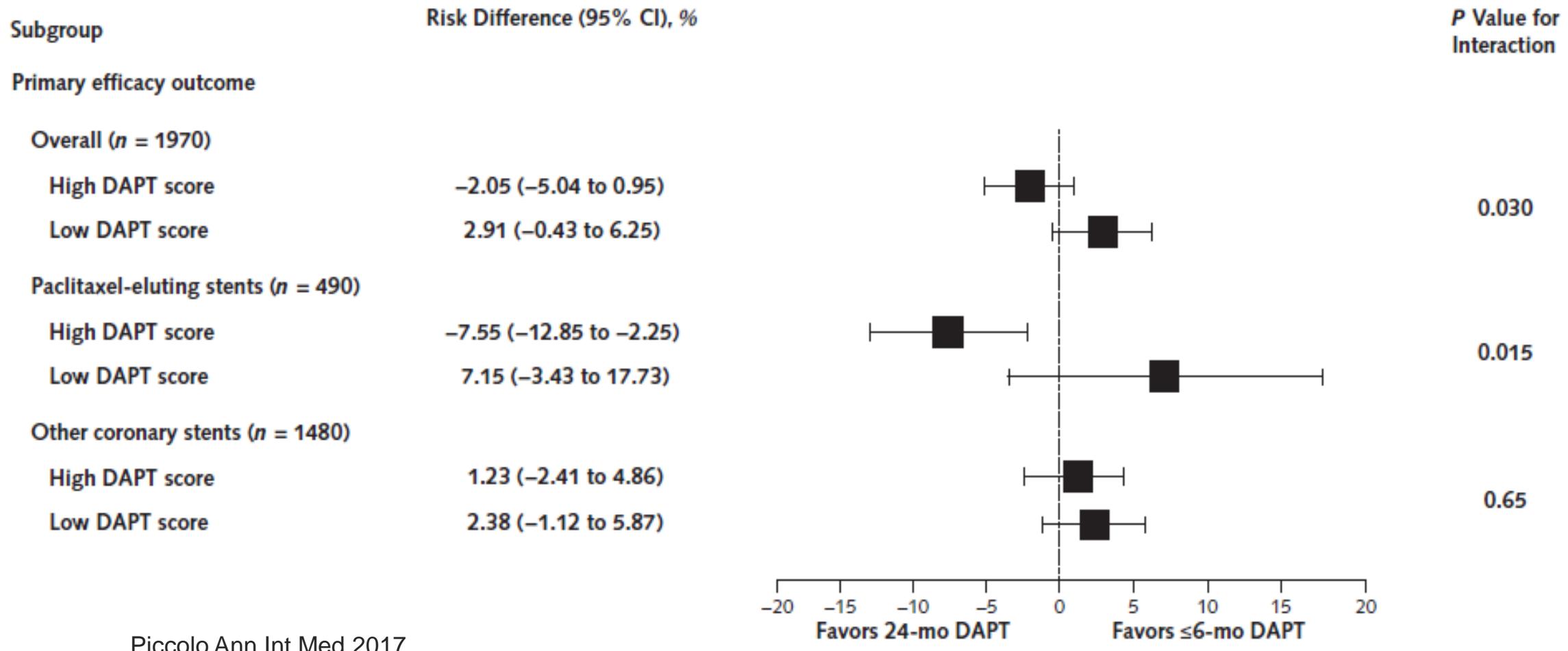
# PARIS: Clotting vs. Bleeding Risk After PCI



# DAPT SCORE: net benefit

Predictors of Events <sup>a</sup>	Predictors of Myocardial Infarction or Stent Thrombosis <sup>b</sup>		Predictors of Moderate or Severe Bleeding <sup>c</sup>	
	HR (95% CI)	P Value	HR (95% CI)	P Value
Continued thienopyridine vs placebo	0.52 (0.42-0.65)	<.001	1.66 (1.26-2.19)	<.001
Myocardial infarction at presentation	1.65 (1.31-2.07)	<.001		
Prior PCI or prior myocardial infarction	1.79 (1.43-2.23)	<.001		
History of CHF or LVEF <30%	1.88 (1.35-2.62)	<.001		
Vein graft stent	1.75 (1.13-2.73)	.01		
Stent diameter <3 mm	1.61 (1.30-1.99)	<.001		
Paclitaxel-eluting stent	1.57 (1.26-1.97)	<.001		
Cigarette smoking	1.40 (1.11-1.76)	.01		
Diabetes mellitus	1.38 (1.10-1.72)	.01		
Age, per 10 y			1.54 (1.34-1.78)	<.001
Peripheral arterial disease	1.49 (1.05-2.13)	.03	2.16 (1.46-3.20)	<.001
Hypertension	1.37 (1.03-1.82)	.03	1.45 (1.00-2.11)	.05
Renal insufficiency/failure	1.55 (1.03-2.32)	.04	1.66 (1.04-2.66)	.03

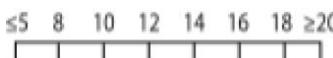
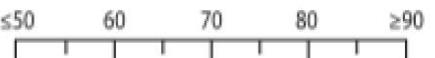
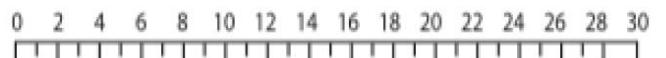
# Limitation of the DAPT score



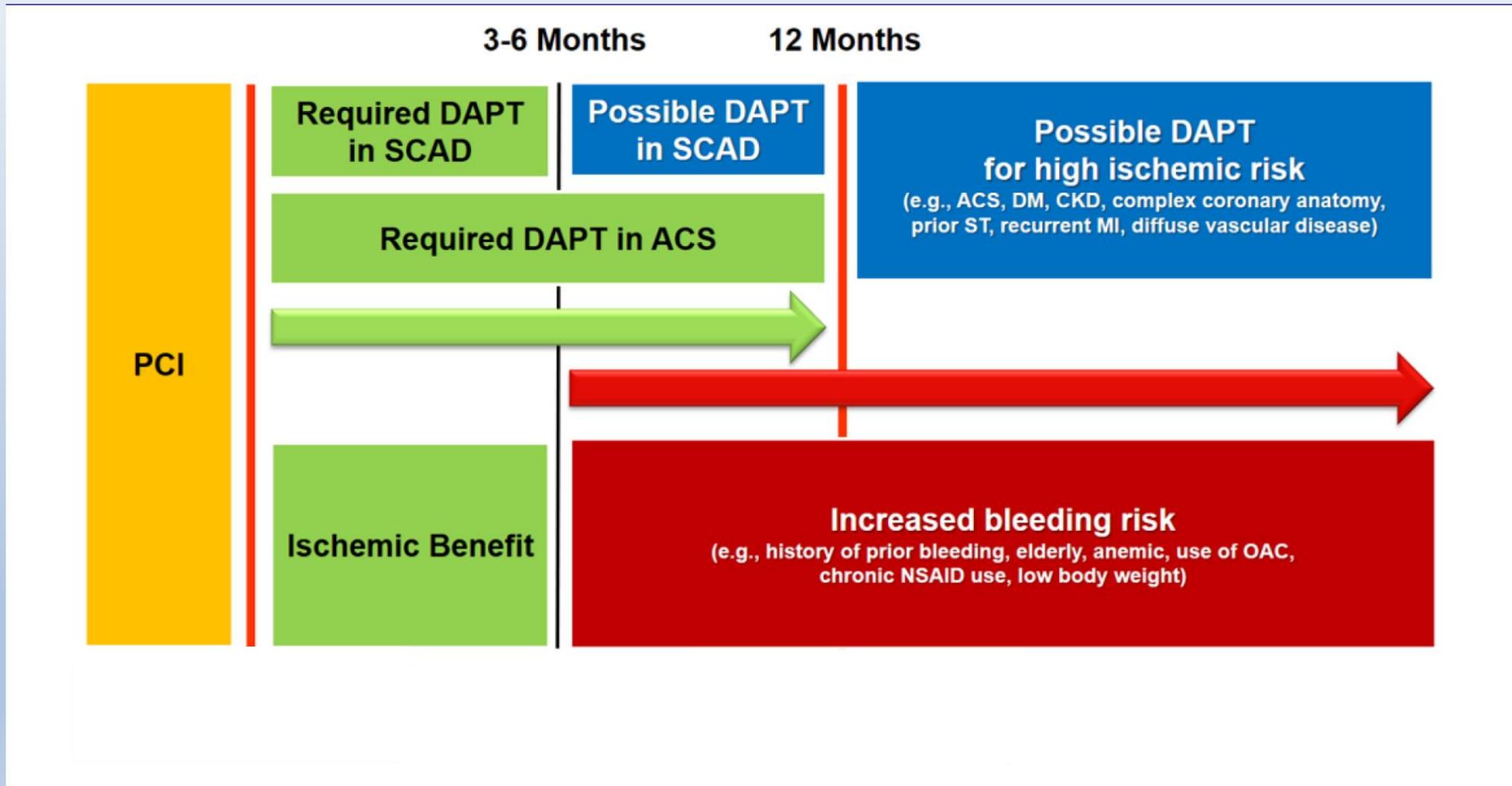
# PRECISE DAPT SCORE: focus on bleeding risk (TIMI major and minor)

	Hazard ratio (95% CI)	p value
Age (for each increase of 10 years)	1.34 (1.11-1.48)	0.005
Previous bleeding	4.14 (1.22-14.02)	0.023
White-blood-cell count (for each increase of $10^3$ cells per $\mu\text{L}$ )	1.06 (0.99-1.13)	0.078
Haemoglobin at baseline (for each increase of 1 g/dL)	0.67 (0.53-0.84)	0.001
Creatinine clearance (for each increase of 10 mL/min)	0.90 (0.82-0.99)	0.004

# Thang điểm DAPT và PRECISE-DAPT

	PRECISE-DAPT score <sup>18</sup>	DAPT score <sup>15</sup>
Time of use	At the time of coronary stenting	After 12 months of uneventful DAPT
DAPT duration strategies assessed	Short DAPT (3–6 months) vs. Standard/long DAPT (12–24 months)	Standard DAPT (12 months) vs. Long DAPT (30 months)
Score calculation <sup>a</sup>	<p>HB      </p> <p>WBC     </p> <p>Age      </p> <p>CrCl     </p> <p>Prior Bleeding      No      Yes</p> <p>Score Points      </p>	<p>Age  <math>\geq 75</math>      -2 pt  <math>65 \text{ to } &lt; 75</math>      -1 pt  <math>&lt; 65</math>      0 pt</p> <p>Cigarette smoking      +1 pt</p> <p>Diabetes mellitus      +1 pt</p> <p>MI at presentation      +1 pt</p> <p>Prior PCI or prior MI      +1 pt</p> <p>Paclitaxel-eluting stent      +1 pt</p> <p>Stent diameter <math>&lt; 3 \text{ mm}</math>      +1 pt</p> <p>CHF or LVEF <math>&lt; 30\%</math>      +2 pt</p> <p>Vein graft stent      +2 pt</p>
Score range	0 to 100 points	-2 to 10 points
Decision making cut-off suggested	Score $\geq 25 \rightarrow$ Short DAPT Score $< 25 \rightarrow$ Standard/long DAPT	Score $\geq 2 \rightarrow$ Long DAPT Score $< 2 \rightarrow$ Standard DAPT
Calculator	<a href="http://www.precisedapscore.com">www.precisedapscore.com</a>	<a href="http://www.daptstudy.org">www.daptstudy.org</a>

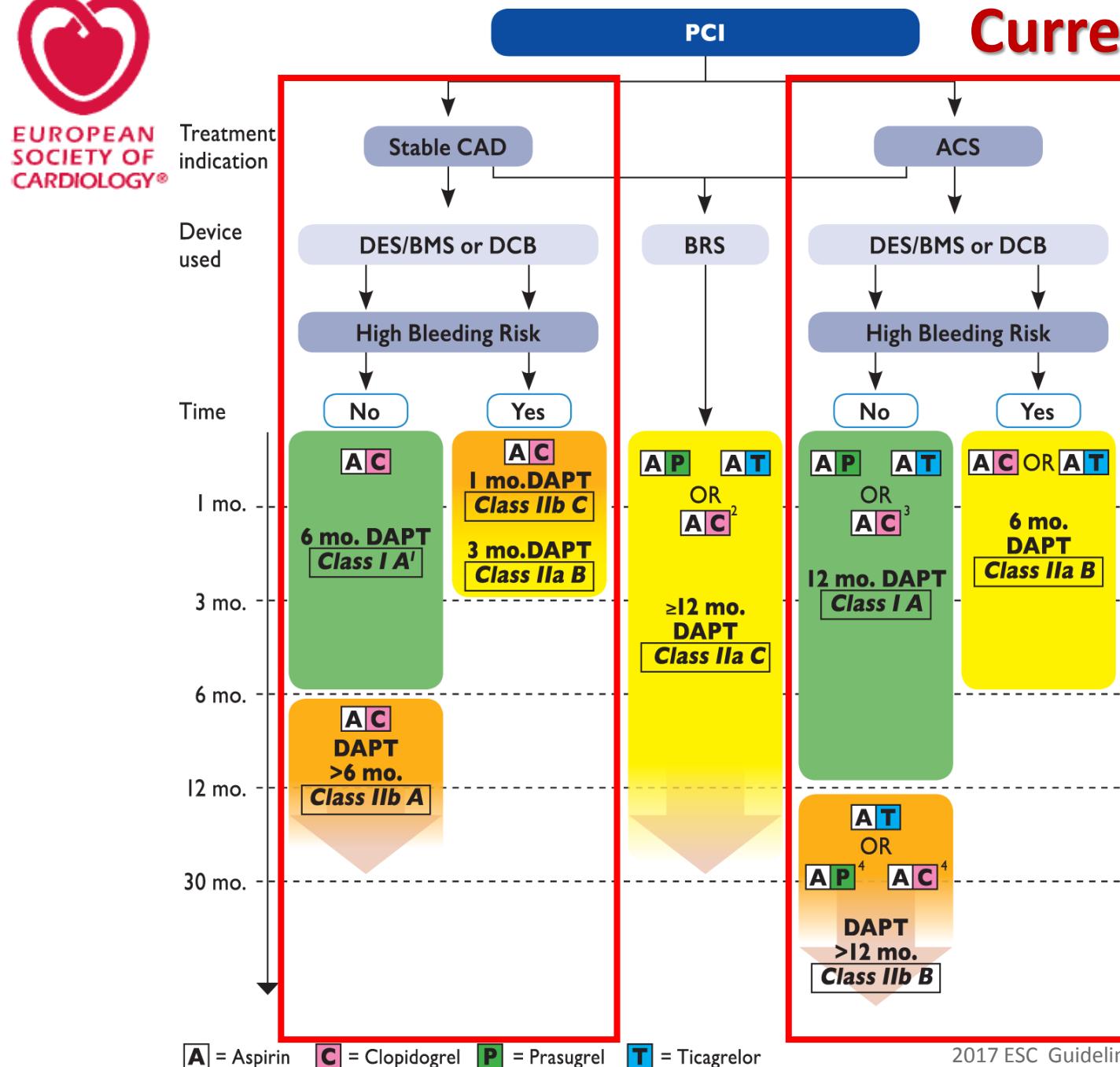
# Optimal DAPT duration after DES Implantation





EUROPEAN  
SOCIETY OF  
CARDIOLOGY®

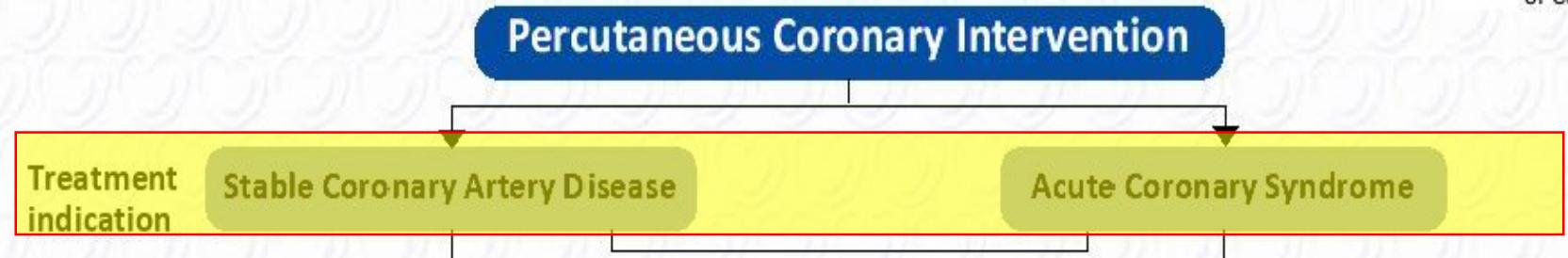
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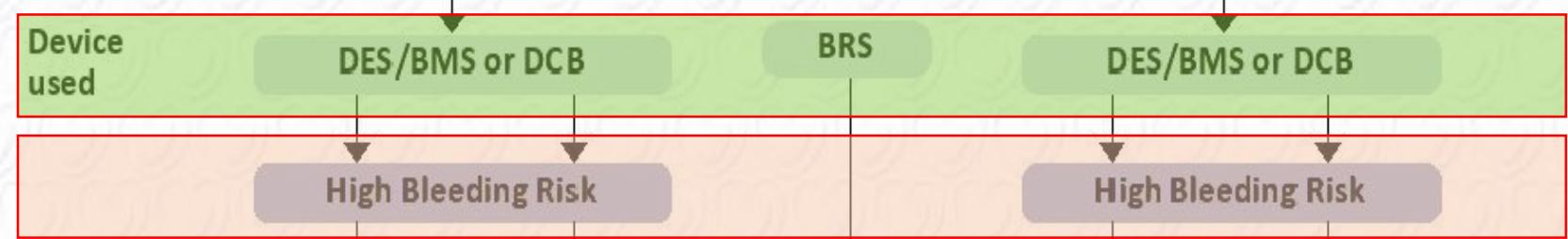
# Algorithm for dual antiplatelet therapy (DAPT) in patients treated with percutaneous coronary intervention



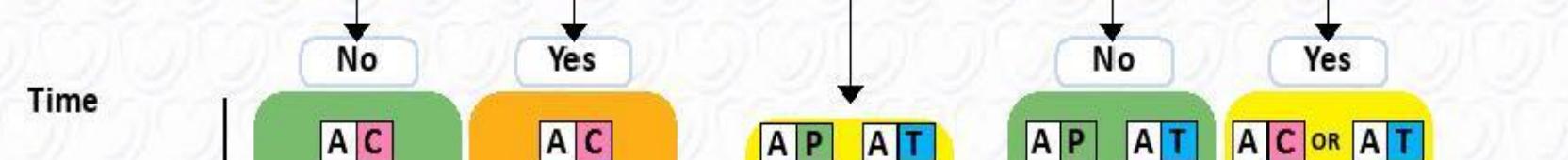
First step



Second step



Third step



XÁC ĐỊNH BỆNH NHÂN  
NGUY CƠ XUẤT HUYẾT CAO  
*High Bleeding Risk- HBR*  
Định nghĩa ARC- HBR

# Heterogeneity of inclusion criteria in current HBR trials

	LEADER S FREE	LEADERS FREE II	ZEUS-HBR	SENIOR	ONYX ONE	MASTER DAPT	COBRA REDUCE	EVOLVE SHORT DAPT	XIENCE 28 XIENCE 90	POEM
BARC 3-5 bleeding @ 1y	7.2%	7.2%	4.2%	3.5%	4.6%	NYK	NYK	NYK	NYK	NYK
Age ≥75 (or >80*)	●	●	●*	●	●	●	●	●	●	●
OAC	●	●	●		●	●	●	●	●	●
Renal failure	●	●			●			●	●	●
Liver disease	●	●			●	●				●
Recent cancer	●	●			●	●				●
Anemia or transfusion	●	●	●		●	●			●	●
Thrombocytopenia	●	●	●		●	●		●	●	●
Stroke or ICH	●	●			●	●		●	●	●
Actionable bleed						●		●	●	
Hospitalization for bleeding	●	●	●		●	●				●
NSAID or steroids	●	●	●		●	●				●
Early planned surgery	●	●			●					●

# The New ARC-HBR Definition - 2019

## The ARC-HBR group:

- Lead Physicians from USA, EU, Asia
- Regulators incl. FDA, PMDA, DEKRA
- Industry (listening)
- Two working meetings:
  - Apr 2018 Washington DC
  - Oct 2018 Paris

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**Circulation**

**WHITE PAPER**

**Defining High Bleeding Risk in Patients Undergoing Percutaneous Coronary Intervention**

A Consensus Document From the Academic Research Consortium for High Bleeding Risk

**ABSTRACT:** Identification and management of patients at high bleeding risk undergoing percutaneous coronary intervention are of major importance, but a lack of standardization in defining this population limits trial design, data interpretation, and clinical decision-making. The Academic Research Consortium for High Bleeding Risk (ARC-HBR) is a collaboration among leading research organizations, regulatory authorities, and physician-scientists from the United States, Asia, and Europe focusing on percutaneous coronary intervention-related bleeding. Two meetings of the 31-member consortium were held in Washington, DC, in April 2018 and in Paris, France, in October 2018. These meetings were organized by the Cardiovascular European Research Center on behalf of the ARC-HBR group and included representatives of the US Food and Drug Administration and the Japanese Pharmaceuticals and Medical Devices Agency, as well as observers from the pharmaceutical and medical device industries. A consensus definition of patients at high bleeding risk was developed that was based on review of the available evidence. The definition is intended to provide consistency in defining this population for clinical trials and to complement clinical decision-making and regulatory review. The proposed ARC-HBR consensus document represents the first pragmatic approach to a consistent definition of high bleeding risk in clinical trials evaluating the safety and effectiveness of devices and drug regimens for patients undergoing percutaneous coronary intervention.

Philip Urban, MD et al

Full author list is available on page 254  
Key Words: clinical trial protocols as topic ■ hemorrhage ■ percutaneous coronary intervention

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**CURRENT OPINION**

**ESC**  
European Heart Journal (2019) 40, 2632–2653  
doi:10.1093/eurheartj/ehz372

**Defining high bleeding risk in patients undergoing percutaneous coronary intervention: a consensus document from the Academic Research Consortium for High Bleeding Risk**

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# **Details of the new ARC-HBR Definition\***

## **One Major or Two Minor Criteria Needed**

### ***Major***

- *Oral anticoagulation*
- *Severe kidney disease*
- *Hemoglobin < 11 g/dL*
- *Severe bleeding < 6M*
- *Low platelet count < 100,000 /uL*
- *Chronic bleeding diathesis*
- *Liver cirrhosis*
- *Active cancer*
- *Spontaneous cerebral bleeding*
- *Traumatic cerebral bleeding*
- *Arterio-venous malformation*
- *Ischemic stroke <6M*

### ***Minor***

- *Age ≥ 75 Y*
- *Moderate kidney disease*
- *Hemoglobin 11 – 12.9 g/dL*
- *Spontaneous bleeding <12M*
- *NSAIDs and Steroid use*
- *Any other ischemic stroke*

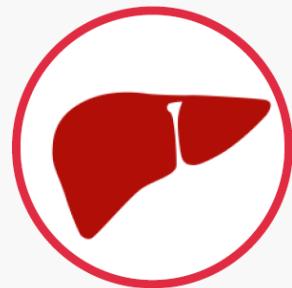
# The ARC-HBR criteria (I)



Age



Renal disease



Liver disease



Active cancer

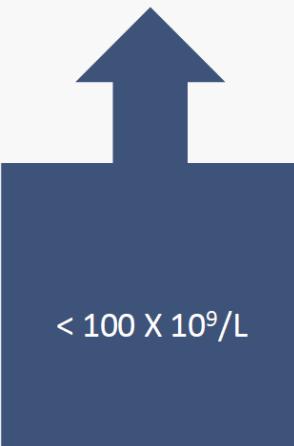
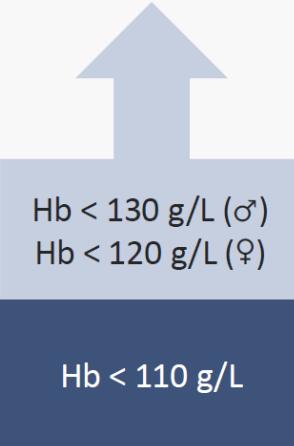
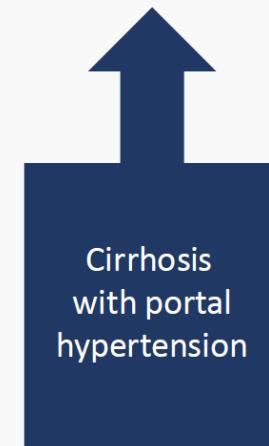
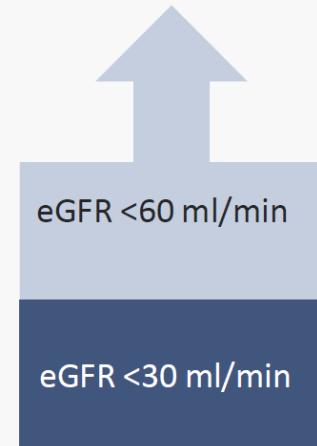
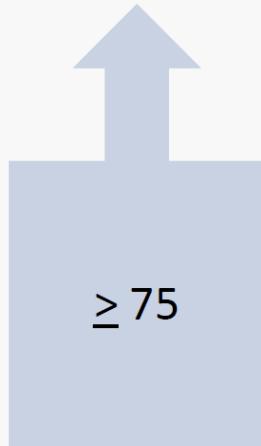


Anemia



Low platelet count

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Major criterion



Minor criterion

# The ARC HBR criteria (II)



Stroke,  
ICH, bAVM



Bleeding  
diathesis



Prior bleeding  
or transfusion



OAC



NSAIDs,  
steroids



Planned surgery on DAPT,  
recent trauma or surgery

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- ▶ Prior spont. ICH
- ▶ Known bAVM
- ▶ Traumatic ICH < 12 months
- ▶ Moderate or severe ischemic stroke < 6 months

Any other prior ischemic stroke

Chronic clinically significant Bleeding diathesis

Spontaneous bleeding + hospital and or transfusion < 6 months or at any time if recurrent

Same, 6-12 months, Not recurrent

Long term after PCI

Chronic use after PCI

- ▶ Non-deferrable Surgery on DAPT
- ▶ Major trauma or surgery in prior 30 days



Major criterion



Minor criterion

# What are the essential results?

## consensus

HBR =  
BARC 3 or 5 bleeding  
risk of  $\geq 4\%$   
and/or  
risk of intracranial  
hemorrhage (ICH)  $\geq 1\%$   
within 1 year after PCI

so...

## major criterion

In isolation, confers:  
1) BARC 3 or 5 bleeding  
risk  
of  $\geq 4\%$  at one year  
and/ or  
2 ) risk of ICH of  $\geq 1\%$   
at one year

and

## minor criterion

In isolation confers  
increased bleeding risk,  
but:  
risk of BARC 3 or 5  
bleeding of  $<4\%$  at one  
year  
and  
risk of ICH  $< 1\%$

**HBR status conferred if:**



1 major criterion

or



2 minor criteria

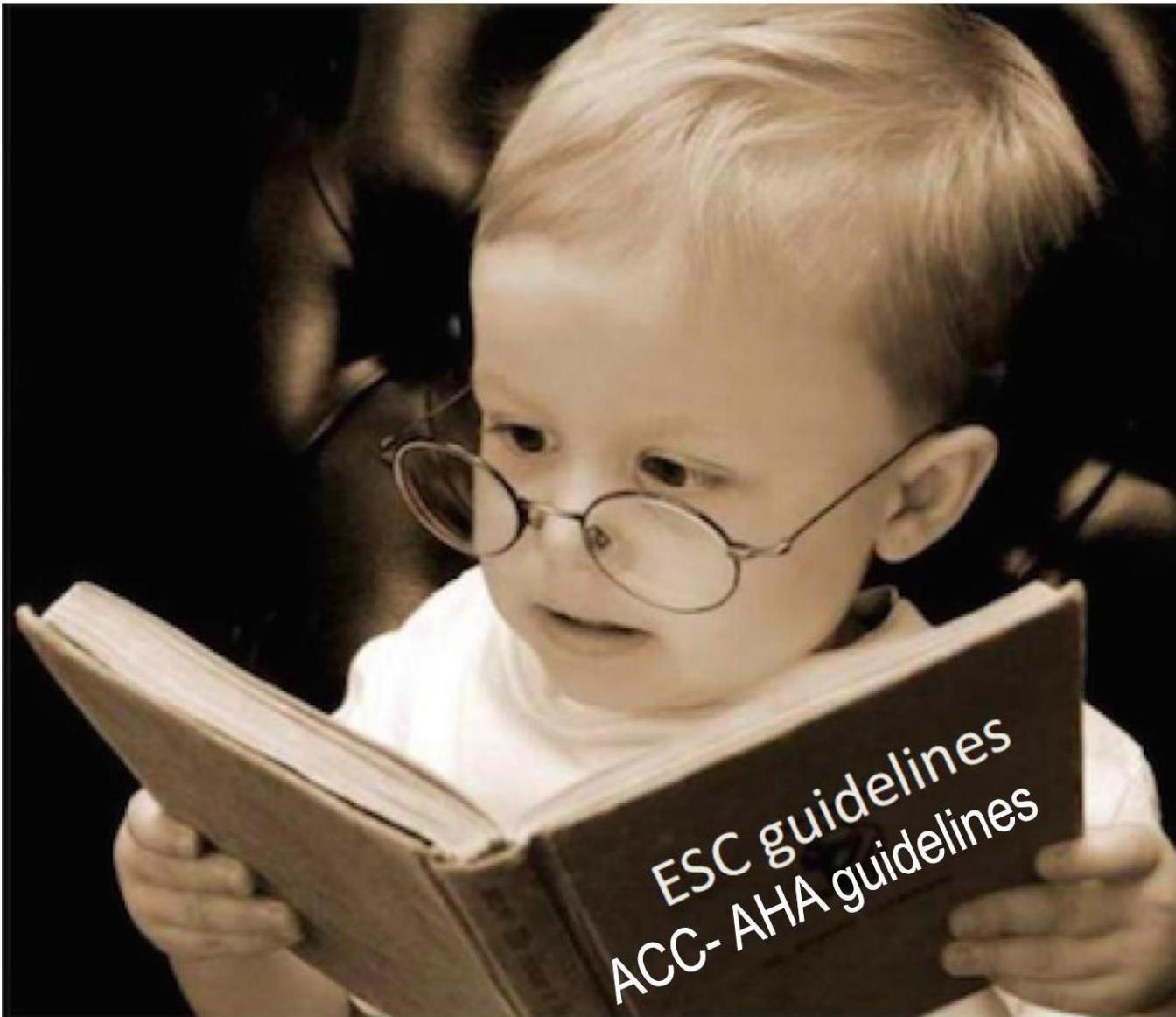
# Summary and Outlook

- The new ARC HBR criteria will constitute an internationally accepted and endorsed standard definition for high-bleeding risk patients.
- The new criteria will allow re-analyses of previous trials to achieve a more appropriate across-trial comparison of HBR patient outcomes.
- **Future trials will use the ARC-HBR trial criteria as a new standard.**
- **The new criteria may help regulators around the globe to consider HBR patients as a new target population for medical device approval.**
- **Global trials conducted in several territories will become possible.**

*This remains an important question  
for not only HBR patients but for  
many patients who may BECOME  
HBR after PCI...*

*Thank you for your attention!*

A/Prof Ho Thuong Dung, HCMC, VN



PGS TS Hồ Thượng Dũng, TPHCM