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Rationale for Drug-Coated Balloon Use in High-Bleeding-Risk Patients

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Disclosure

- No potential conflicts of interest

Major bleeding Definition

Major bleeding rates in PCI patients vary from 1–10% in studies, influenced by differing bleeding definitions and other factors.

Studies consistently link bleeding—regardless of definition—to higher risks of death[18,20], MI[6], stroke[5], and stent thrombosis.

I. Impact of Major Bleeding on Mortality in Registries and Randomized Trials of Patients With Acute Coronary Syndromes or Undergoing Percutaneous Coronary Interventions

Study	Setting, Design	Primary Definition*	Patients	Patients With Bleeding, n (%)	Outcomes in Patients With Major or Severe Bleeding vs No Bleeding			
					ly Deaths (In Hospital or at 30 d)		Deaths up to 1 y	
					Death Rates, %	Adjusted Risk Ratio for Death (95% CI)	Death Rates, %	Adjusted Risk Ratio for Death (95% CI)
Kinnaird et al,[7] 2003	PCI, registry	TIMI	10 974	588 (5.4)	7.5 vs 0.6	3.5 (1.9–6.7)	17.2 vs 5.5	Not significant†
GRACE,[10] 2003	ACS, registry	GRACE	24 045	933 (3.9)	18.6 vs 5.1	1.6 (1.2–2.3)	…	…
GRACE,[21] 2007	ACS, registry	GRACE	40 087	1140 (2.8)	20.9 vs 5.6	1.9 (1.6–2.2)	7.9 vs 5.2	0.8 (0.6–1.0)
REPLACE-2,[25] 2007	PCI, RCT	REPLACE-2/ISAR-REACT 3	6001	195 (3.2)	5.1 vs 0.2	…	8.7 vs 1.9	2.7 (1.4–4.9)
Rao et al,[6] 2005	NSTE-ACS, meta-analysis of RCTs	GUSTO	26 452	107 (0.4)	25.7 vs 2.9	10.6 (8.3–13.6)	35.1 vs 4.2	7.5 (6.1–9.3)
Eikelboom et al,[5] 2006	NSTE-ACS, meta-analysis of RCTs/registry	CURE	34 146	783 (2.3)	12.8 vs 2.5	9.8 (7.5–12.7)	4.6 vs 2.9‡	1.9 (1.3–2.8)
ACUITY,[9] 2007	NSTE-ACS, RCT	ACUITY	13 819	644 (4.7)	7.3 vs 1.2	7.6 (4.7–12.2)	…	3.5 (2.7–4.4)
Ndrepepa et al,[15] 2008	PCI, meta-analysis of RCTs	TIMI	5384	215 (4.0; n=59 major/n=156 minor)	…	…	12.2 vs 3.3	4.1 (2.1–8.3)
EVENT,[26] 2009	PCI, registry	TIMI	5961	(3.0 overall: 0.7 major, 2.3 minor)	…	…	15.6 vs 2.4	3.8 (2.5–5.9)
OASIS-5,[27] 2009	NSTE-ACS, RCT	ESSENCE	20 078	990 (4.9): major, 423 (2.1) minor	8.4 vs 2.7	3.5 (2.6–4.6)	14.3 vs 5.4	3.1 (2.6–3.8)
Amlani et al,[28] 2010	STEMI, registry	Protocol defined	1389	152 (10.9)	19.7 vs 8.2	2.8 (1.8–4.3)	…	…
ISAR-REACT 3,[29] 2010	PCI, RCT	REPLACE-2/ISAR-REACT 3	4570	555 (12.1) 174 major/381 minor	…	…	5.2 vs 1.3	4.1 (2.6–6.5)

CI indicates confidence interval; PCI, percutaneous coronary intervention; TIMI, Thrombolysis in Myocardial Infarction; ACS, acute coronary syndrome; GRACE, Global Registry of Acute Coronary Events; RCT, randomized controlled trial; REPLACE-2, Randomized Evaluation in PCI Linking Angiomax to Reduced Clinical Events; ISAR-REACT 3, Intracoronary Stenting and Antithrombotic Regimen: Rapid Early Action for Coronary Treatment; NSTE, non–ST-elevation; GUSTO, Global Use of Strategies to Open Occluded Arteries; CURE, Clopidogrel in Unstable Angina to Prevent Recurrent Events; ACUITY, Acute Catheterization and Urgent

5. Eikelboom JW, Mehta SR, Anand SS, Xie C, Fox KA, Yusuf S. Adverse impact of bleeding on prognosis in patients with acute coronary syndromes. **Circulation**. 2006; *114*:774–782
6. Rao SV, O'Grady K, Pieper KS, Granger CB, Newby LK, Van de Werf F, Mahaffey KW, Califf RM, Harrington RA. Impact of bleeding severity on clinical outcomes among patients with acute coronary syndromes. **Am J Cardiol**. 2005; *96*:1200–1206
9. Manoukian SV, Feit F, Mehran R, Voeltz MD, Ebrahimi R, Hamon M, Dangas GD, Lincoff AM, White HD, Moses JW, King SB, Ohman EM, Stone GW. Impact of major bleeding on 30-day mortality and clinical outcomes in patients with acute coronary syndromes: an analysis from the ACUITY trial. **J Am Coll Cardiol**. 2007; *49*:1362–1368
18. Rao SV, Eikelboom JA, Granger CB, Harrington RA, Califf RM, Bassand JP. Bleeding and blood transfusion issues in patients with non-ST-segment elevation acute coronary syndromes. **Eur Heart J**. 2007; *28*:1193–1204.
19. Mehta SK, Frutkin AD, Lindsey JB, House JA, Spertus JA, Rao SV, Ou FS, Roe MT, Peterson ED, Marso SP. Bleeding in patients undergoing PTCA: the development of a clinical risk algorithm . **Circ Cardiovasc Interv**. 2009; *2*:222–229
20. Doyle BJ, Rihal CS, Gastineau DA, Holmes DR. Bleeding, blood transfusion, and increased mortality after percutaneous coronary intervention: implications for contemporary practice. **J Am Coll Cardiol**. 2009; *53*:2019–2027

No universal major bleeding definition exists, with over 10 different versions used in trials and registries, reflecting a lack of standardization..

Current definitions mix lab values (e.g., haemoglobin drops) and clinical events (e.g., transfusions, surgery, tamponade, hematomas).

Each definition combines these elements differently and categorizes severity inconsistently.

33. Steinhubl SR, Kastrati A, Berger PB. Variation in the definitions of bleeding in clinical trials of patients with acute coronary syndromes and undergoing percutaneous coronary interventions and its impact on the apparent safety of antithrombotic drugs. Am Heart J. 2007; *154*:3–11.
34. Schulman S, Kearon C. Definition of major bleeding in clinical investigations of antihemostatic medicinal products in non-surgical patients. J Thromb Haemost. 2005; *3*:692–694.
35. Cohen M, Alexander KP, Rao SV. Bleeding after antithrombotic therapy in patients with acute ischemic heart disease: is it the drugs or how we use them?J Thromb Thrombolysis. 2008; *26*:175–182

Bleeding definitions

Heterogeneity Across Trials 2

One of the most widely used definitions over the last three decades has been the Thrombolysis in Myocardial Infarction (TIMI) definition of bleeding.[8]

Originally designed for STEMI patients receiving thrombolytics, this definition classified bleeding as major or minor based primarily on haemoglobin and haematocrit levels.

It primarily relied on Hb/Hct drops (major bleeding: >5 g/dL Hb decrease) but faced criticism for its arbitrary thresholds and lack of clinical event emphasis.

TIMI

Major bleeding:
- Intracranial bleeding
- Clinically overt haemorrhage with >5 g/dL decrease in Hb
- Fatal bleeding (death within 7 days)

Minor bleeding:
- Clinically overt haemorrhage with <5 g/dL fall in Hb

Requiring medical attention: (and does not meet criteria for major or minor bleeding)
- Bleeding requiring intervention
- Bleeding leading to prolonged hospitalisation
- Bleeding prompting evaluation

Minimal bleeding:
- Any overt bleeding that does not meet any of the above criteria

8. Bovill EG et al. Hemorrhagic events during therapy with recombinant tissue- type plasminogen activator, heparin, and aspirin for acute myocardial infarction. Results of the Thrombolysis in Myocardial Infarction (TIMI), Phase II Trial. Ann Intern Med. 1991;115(4):256-65

Bleeding definitions

Heterogeneity Across Trials 3

The Global Use of Strategies to Open Occluded Arteries (GUSTO) definition of bleeding has also been widely used.[9]

Developed for thrombolysis in STEMI, this definition graded bleeding severity by clinical impact alone, without requiring Hb changes or transfusion quantification.

In ACS patients, while both definitions predict acute outcomes, GUSTO-defined bleeding shows persistent risk unlike TIMI.[10]

GUSTO

Severe or life-threatening:

- Intracranial bleeding
- Bleeding leading to haemodynamic compromise requiring treatment

Moderate:

- Bleeding requiring blood transfusion but not leading to haemodynamic compromise

Mild:

- Bleeding that does not meet the above criteria

9. An international randomized trial comparing four thrombolytic strategies for acute myocardial infarction. The GUSTO investigators. N Engl J Med. 1993;329(10): 673-82.
10. Rao SV et al. A comparison of the clinical impact of bleeding measured by two different classifications among patients with acute coronary syndromes. J Am Coll Cardiol. 2006;21;47(4):809-16.

To address TIMI/GUSTO limitations, some trials have integrated both lab and clinical parameters, including.

- The Clopidogrel in Unstable Angina to Prevent Recurrent Events (CURE),
- Acute Catheterization and Urgent Intervention Triage Strategy (ACUITY)
- Organization for the Assessment of Strategies for Ischemic Syndromes (OASIS)
- Safety and Efficacy of Enoxaparin in PCI Patients, an International Randomized Evaluation (STEEPLE)
- Platelet Inhibition and Patient Outcomes (PLATO)
- International Society on Thrombosis and Haemostasis - (ISTH)

Bleeding definitions

Heterogeneity Across Trials 5

The Bleeding Academic Research Consortium (BARC) have also made efforts to create a universal bleeding definition.[7]

Correlates bleeding severity with prognosis

Guides clinical decision-making

Demonstrating good correlation with clinical outcome.

BARC

Type 0:
- No bleeding

Type 1:
- Bleeding that is not actionable

Type 2:
- Clinically overt haemorrhage that does not meet criteria for Type 3, 4, or 5

Type 3 (a):
- Overt bleeding + Hb drop between 3–5 g/dL

Type 3 (b):
- Overt bleeding + Hb drop >5 g/dL
- Cardiac tamponade
- Bleeding requiring surgical intervention
- Bleeding requiring intravenous vasoactive drugs

Type 3 (c):
- Intracranial
- Intraocular

Type 4:
- CABG related bleeding

Type 5:
- Fatal bleeding

9. An international randomized trial comparing four thrombolytic strategies for acute myocardial infarction. The GUSTO investigators. N Engl J Med. 1993;329(10): 673-82.
10. Rao SV et al. A comparison of the clinical impact of bleeding measured by two different classifications among patients with acute coronary syndromes. J Am Coll Cardiol. 2006;21;47(4):809-16.

A pooled analysis by Ndrepepa et al.[18] of 12,459 patients undergoing PCI:
BARC Class ≥2 strongly predicted 1-year mortality (HR 2.7, 95% CI 2.0-3.6.
BARC Class ≥3 showed even stronger association (HR 3.2, 95% CI 2.3-4.4, p<0.001)

• 18. Ndrepepa G et al. Validation of the Bleeding Academic Research Consortium Definition of Bleeding in Patients With Coronary Artery Disease Undergoing Percutaneous Coronary Intervention. Circulation. 2012;125(11):1424-31

Cohort study by Matic et al.[19] (n=1,808 STEMI patients) showed graded mortality risk by BARC class:
BARC 0/1: 11.5% 1-year mortality
BARC 3b: 43.5% (HR 3.2, 95% CI 1.7-6.2, p<0.0001)

• 19. Matic DM et al. Prognostic implications of bleeding measured by Bleeding Academic Research Consortium (BARC) categorisation in patients undergoing primary percutaneous coronary intervention. Heart Br Card Soc. 2014;100(2):146-52

Study	Study design	Major bleeding definition	Outcome measure	Findings
Ndrepepa et al.[18] (2012)	Pooled analysis of 12,459 patients from six studies	BARC	Bleeding and relationship to mortality	BARC ≥2 bleeding independently associated with 1-year mortality (HR: 2.7, CI: 2.0–3.6, p<0.001)
Matic et al.[19] (2014)	Prospective cohort of 1,808 STEMI patients	BARC	Major bleeding and relationship to mortality	BARC 3a bleeding (HR: 2.0, CI: 1.2–3.4, p=0.012) and BARC 3b bleeding (HR: 3.2, CI: 1.7–6.2, p<0.0001) independently associated with mortality

Regardless of the definition used, bleeding is associated with a significant increase in the risk of death, myocardial infarction (MI), and cerebrovascular accident (CVA).[5,15] Up to 12% of deaths following PCI may relate directly to bleeding complications.[16]

- 5. Kinnaird TD et al. Incidence, predictors, and prognostic implications of bleeding and blood transfusion following percutaneous coronary interventions. Am J Cardiol. 2003;92(8):930-5.
- 15. Rao SV et al. Bleeding and blood transfusion issues in patients with non- ST-segment elevation acute coronary syndromes. Eur Heart J. 2007;28(10): 1193-204.

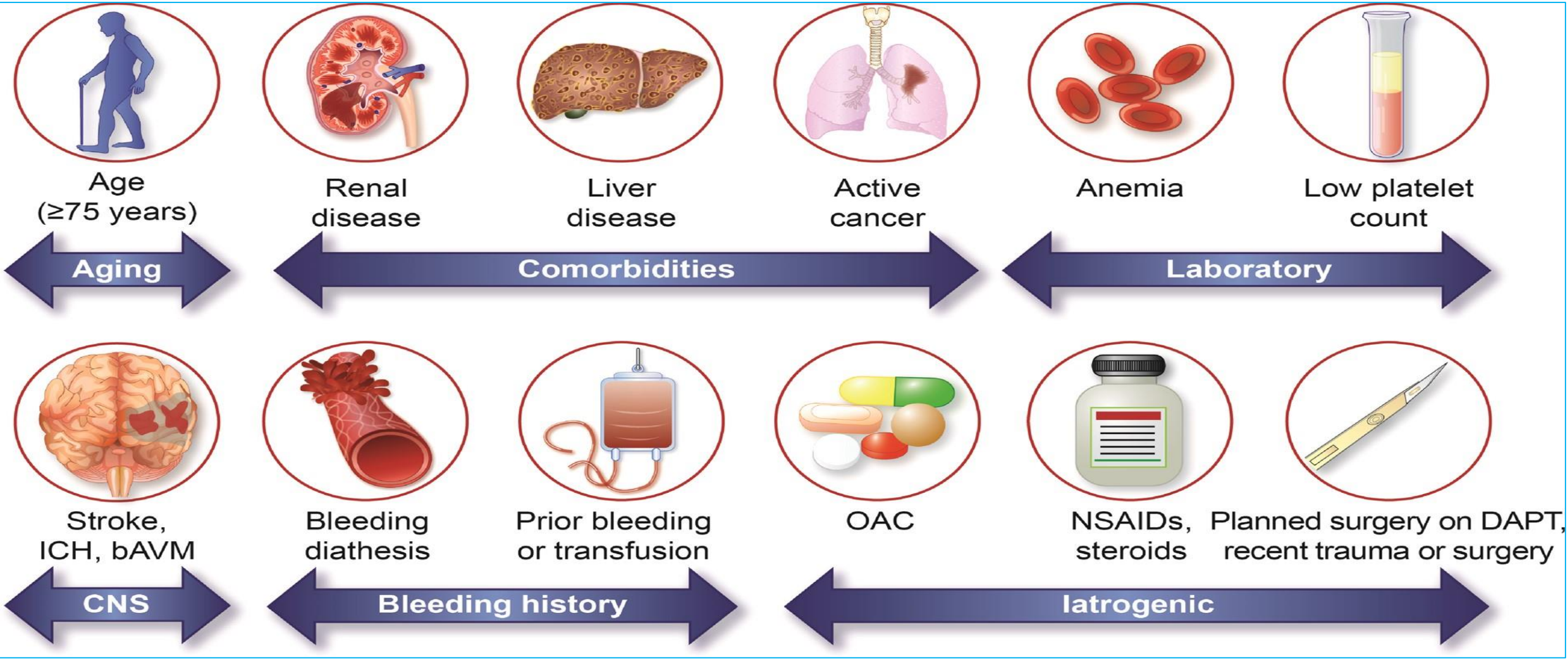
A large meta-analysis by Kwok et al.[17] including 42 studies and >500,000 patients found that bleeding was an independent predictor of death.

Unadjusted analyses: 6× higher death risk

Adjusted for comorbidities: 3× higher risk

- 7. Kwok CS et al. Major bleeding after percutaneous coronary intervention and risk of subsequent mortality: a systematic review and meta-analysis. Open Heart. 2014;1:e000021.

Study	Study design	Major bleeding definition	Outcome measure	Findings
Kwok et al.[17] (2014)	Meta-analysis of 42 studies with 533,333 patients	Variety	Major bleeding and relationship to mortality	Major bleeding independently associated with mortality (HR: 3.3, CI: 2.9–3.8)



Eur Heart J, Volume 40, Issue 31, 14 August 2019, Pages 2632–2653. bAVM indicates brain arteriovenous malformation; CNS, central nervous system; DAPT, dual antiplatelet treatment; ICH, intracranial haemorrhage; NSAID, nonsteroidal anti-inflammatory drug; and OAC, oral anticoagulation.

Identifying HBR predictors is crucial for:
Timely implementation of bleeding prevention strategies
Standardized risk assessment in clinical trials

• 5. Capodanno D, *et al*. Bleeding avoidance strategies in percutaneous coronary intervention. Nature Reviews Cardiology. 2022; 19: 117–132

Bleeding risk scores vary by:
Setting (in-hospital vs. outpatient)
Validation cohort
Outcomes (bleeding-only vs. combined ischemic/bleeding)
Methodology (semi-quantitative vs. quantitative)

Among these, guidelines recognize the PRECISE-DAPT, DAPT and CRUSADE scores and the ACR-HBR criteria

Study (year)	Derivation	Number of items evaluated	Bleeding outcome	Ref.
CRUSADE (2009)	NSTEMI cohort	8	In-hospital major bleeding	11
ACUITY (2010)	ACS cohort	7	30-day major bleeding	12
PRECISE-DAPT (2017)	PCI cohort	5	Out-of-hospital major bleeding	13
ARC-HBR criteria (2019)	Expert consensus	20	Major bleeding at 1 year	14
ARC-HBR trade-off model (2021)	PCI cohort	8	Major bleeding at 1 year	15
BleeMACS (2018)	ACS cohort	7	Major bleeding at 1 year	16
DAPT (2016)	PCI cohort	9	Major bleeding at 1 year	17
PARIS (2016)	PCI cohort	6	Major bleeding at 2 years	18
REACH (2010)	Cohort at risk of or with stable CAD	9	Major bleeding at 2 years	19
CREDO-Kyoto (2018)	PCI cohort	7	Moderate or severe bleeding at 3 years	20

ACS, acute coronary syndromes; ARC-HBR, Academic Research Consortium for High Bleeding Risk; CAD, coronary artery disease; DAPT, dual antiplatelet therapy; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention.

HBR pts undergoing PCI

Bleeding reduction strategies

BEFORE PCI

1. Consider **non-invasive testing** (i.e. stable patients or low risk NSTE-ACS)
2. **Bleeding risk** stratification
3. Optimal **timing of PCI** according to the clinical setting and concomitant ATT (i.e. OAC or fibrinolysis)
4. **Anticoagulation** according to the clinical setting and time to PCI (i.e. UFH or fondaparinux)
5. **Antiplatelet** according to clinical setting and time to PCI (i.e. pre-test PCI probability)

DURING PCI

1. **Radial** access site
2. Optimal **haemostasis** of the arterial acces site (i.e. precise puncture and use of vascular closure devices)
3. Optimal **anticoagulation** (i.e. avoid heparin crossover and adjust dosage according to the concomitant ATT)
4. Optimal **antiplatelet** therapy (i.e. use iv antiplatelets in selected clinical scenarios or bailout situations)
5. Avoid **unnecessary PCI** (i.e. non-prognostic PCI or asymptomatic patients)
6. Avoid **high-risk PCI** when possible (i.e. double stent tecniques)
7. Optimal **stent** selection
8. Stent **optimization** (i.e. use of intravascular imaging)
9. Consider **mechanical circulatory support** in selected patients

DCB

AFTER PCI

1. Periodic assessment of **bleeding risk**
2. Consider DAPT **shortening or de-escalation** of P2Y12 inhibitors
3. Use **proton pump inhibitors**
4. Consider using **platelet function or genetic testing**

DCB

Capodanno D, et al. Bleeding avoidance strategies in percutaneous coronary intervention. Nat Rev Cardiol. 2022 Feb;19(2):117-132

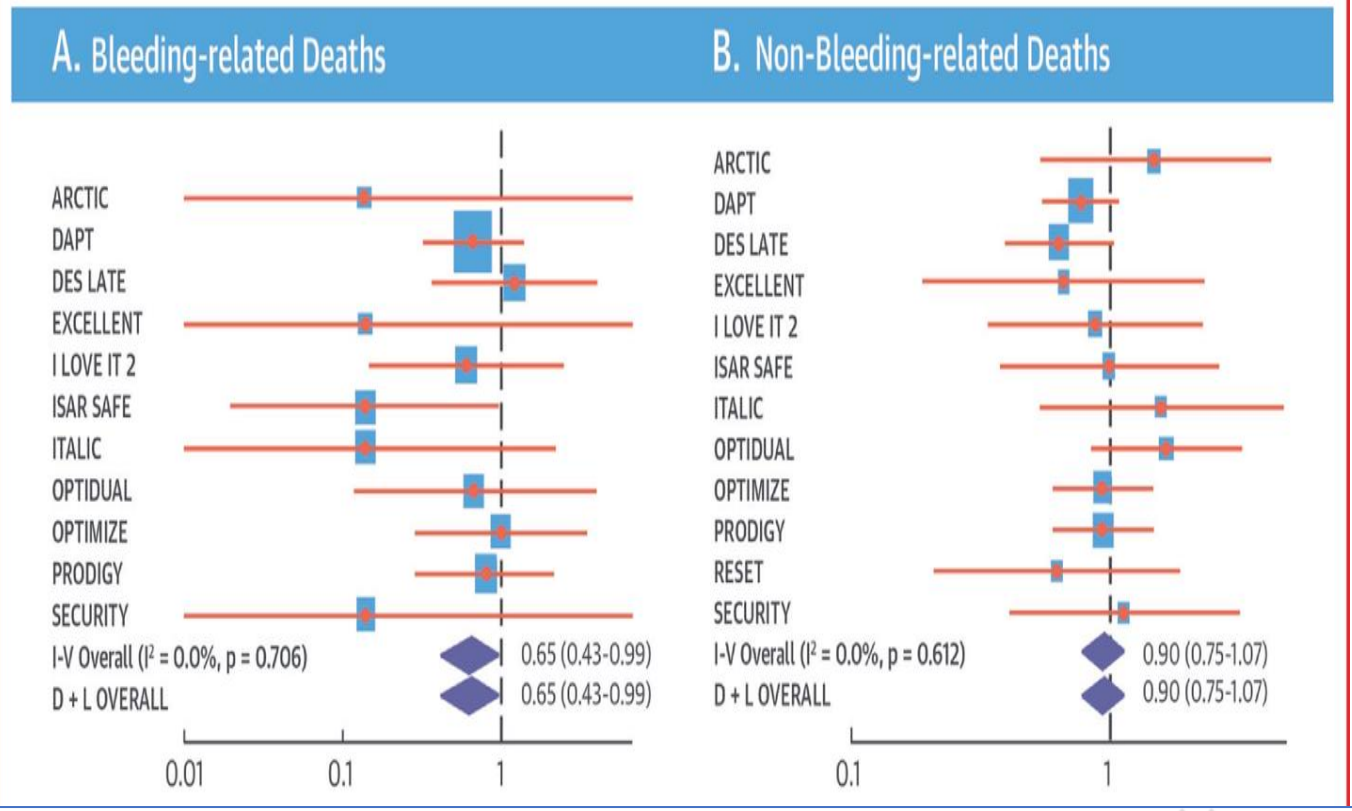
DCB allows shorter DAPT vs DES and may reduce thrombotic risk due to the absence of a permanent implant.

Key advantages of DEB over DES

- Avoids stent thrombosis risk
- Enables shorter DAPT duration
- Rapid high-concentration drug delivery
- No durable polymers/stent struts[6,7]
- Particularly promising for AMI cancer patients

- 6. Jeger RV, Eccleshall S, Wan Ahmad WA, et al. Drug-coated balloons for coronary artery disease: third report of the International DCB Consensus Group. JACC Cardiovasc Interv. 2020;13(12):1391–402.
- 7. Buccheri D, Lombardo RM, Cortese B. Drug-coated balloons for coronary artery disease: current concepts and controversies. Future Cardiol. 2019;15(6):437–54.
- 9. Mehran R, Rao SV, Bhatt DL, et al. Standardized bleeding definitions for cardiovascular clinical trials: a consensus report from the Bleeding Academic Research Consortium. Circulation. 2011;123(23):2736–47.

CENTRAL ILLUSTRATION: Estimates of Risk in the Intention-to-Treat Population for Bleeding-Related Deaths and Deaths Not Related to Bleeding Between Shorter and Longer Dual-Antiplatelet Therapy



Palmerini, T. et al. JACC 2017;69(16):2011-22

Drug-coated balloon for treatment of de-novo coronary artery lesions in patients with HBR: DEBUT trial

Primary endpoints	DCB[102]	BMS[106]	p-value
MACE	1 (1 %)	15 (14 %)	0.00034
Single components of MACE			
Ischemia-driven TLR	0	6 (6 %)	0.015
Cardiac death	1 (1 %)	6 (6 %)	0.061
Non-fatal MI	0	6 (6 %)	0.015
Secondary endpoints			
Thrombosis	0	2 (2%)	
Bleeding events	13 (13%)	11 (10%)	0,59

First RCT evaluating 1-month DAPT in HBR patients

220 HBR patients, 208 randomized post pre-dilatation:
- DCB group: 102 patients
- BMS group: 106 patients

DAPT: 1 month in both groups

Rissanen T et al. The Lancet 2019; 394(10194): 230-9

DCB for Small CAD in Patients With and Without HBR in the BASKET-SMALL 2 Trial

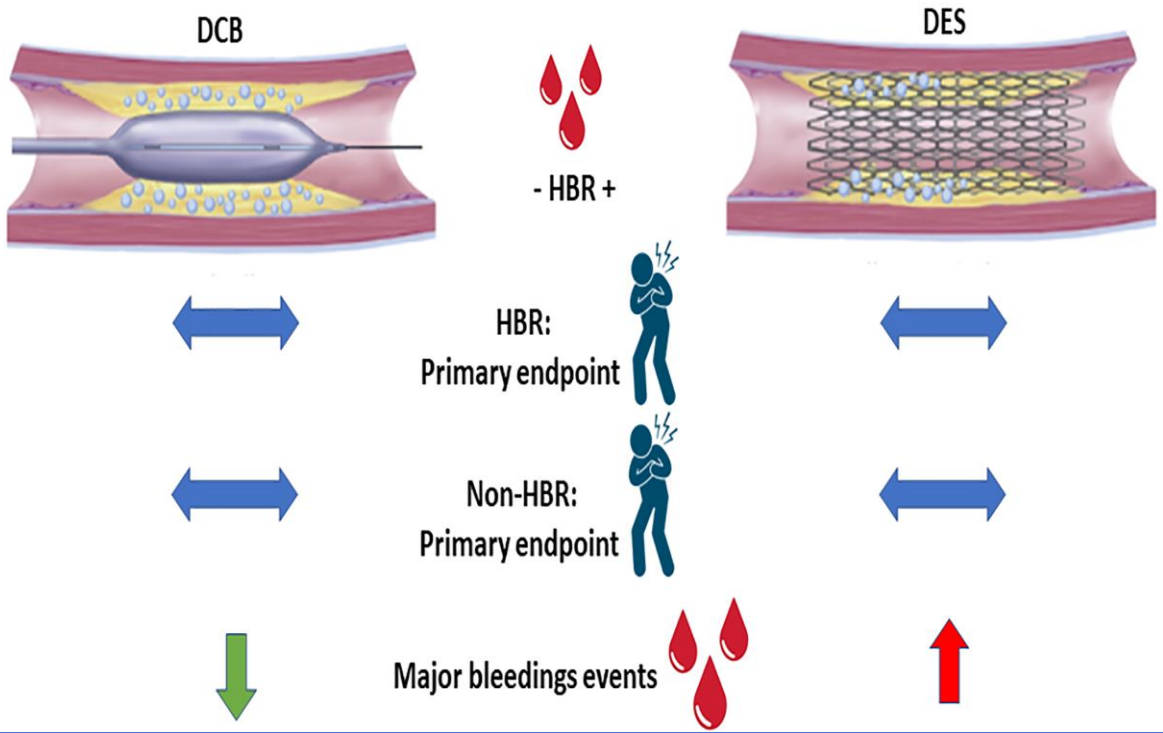
Large multi-center, randomized, controlled, non-inferiority trial (BASKET-SMALL 2) (n=758)

Efficacy and safety of DCBs versus second-generation DESs in small vessel coronary artery disease (<3 mm)

Primary endpoint: composite of cardiac death, non-fatal myocardial infarction, and target vessel revascularization during 3 years

Prespecified subgroup analysis in patients with and without high bleeding risk (HBR)

155 (20%) patients with HBR, 66 randomized to DCB and 89 to DES implantation.



Pts with HBR had higher mortality at 3 years (*P*<0.001)

Rates of major bleeding tended to be lower after DCB versus DES (*P*=0.064)

Major adverse cardiac events between DCB and DES were similar (*P*=0.863)

Scheller B, et all; Circ Cardiovasc Interv. 2022 Apr;15(4):e011569.

PCI with DCB-only strategy combined with SART in patients at HBR: **Single centre experience**

Included DCB-treated patients with stable CAD and ACS discharged on SAPT (periprocedural DAPT allowed)

11% were HBR; 65% on anticoagulation

Anticoagulated patients:

- 42% received ≤1 month SAPT before OAC monotherapy
- 5% discontinued all antiplatelets post-discharge

2011-2020
7565 PCIs

2184 DCB-only PCIs
(29% of total PCIs)

232 DCB-only PCIs followed by SAPT-only (11% of total DCB-only PCIs)

229 DCB-only PCIs followed by SAPT-only with complete follow-up

MACE, was studied at 12 months.

MACE was defined as a composite of cardiovascular death, myocardial infarction (MI) and target lesion revascularization (TLR).

Secondary end points was studied at 12 and 24 months

Secondary end points consisted of BARC class 2-5 bleedings, acute or subacute target vessel closure, target vessel revascularization (TVR), hospitalization for urgent revascularization, stroke and MACE at 24 months.

Räsänen, A et al. Catheter Cardiovasc Interv. 2023;101:569–578.

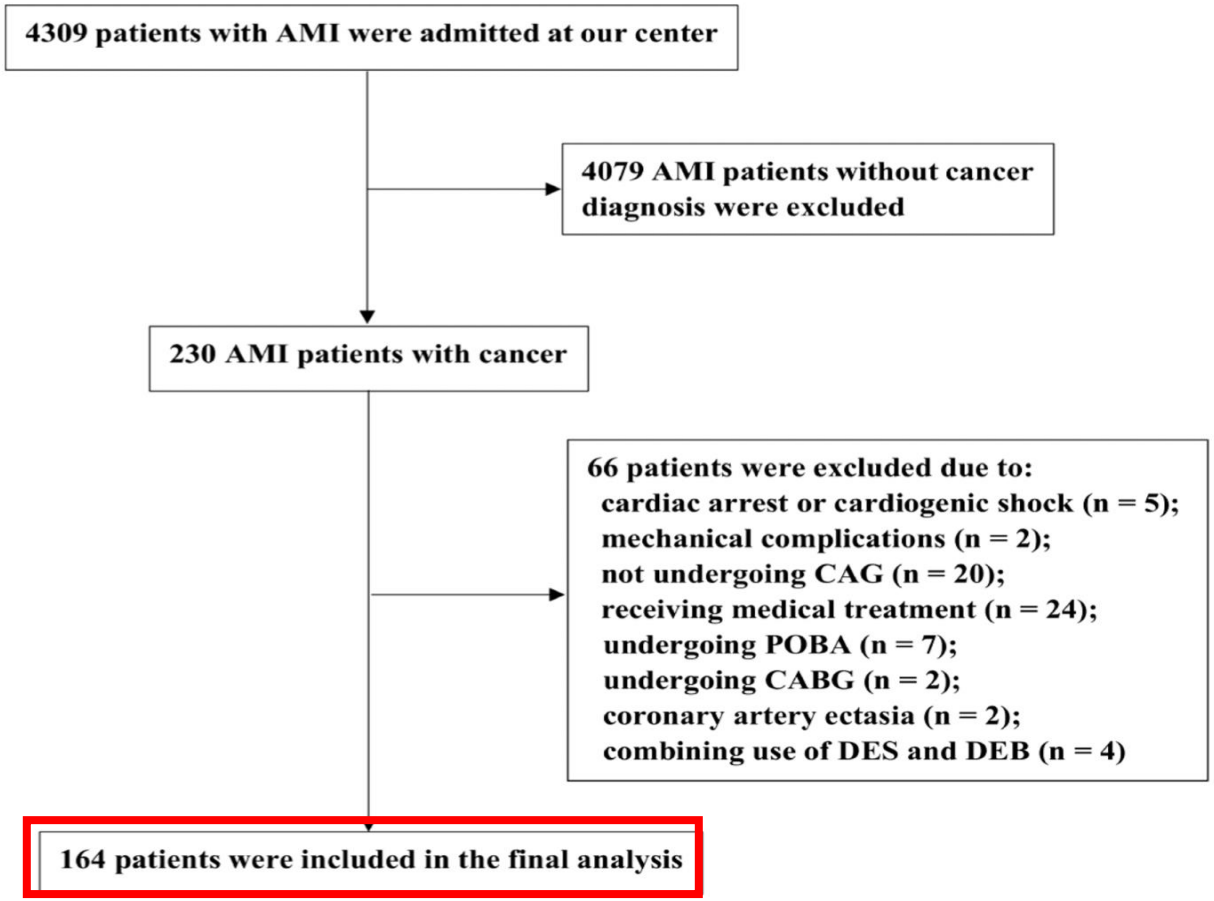
PCI with DCB-only strategy combined with SART in patients at HBR: Single centre experience

	1 m %	12 m %	24 m %
MACE rate (%)	0.0	4.7	8.1
Stable CAD	0.0	1.4	2.7
ACS	0.0	7.1	12.1
Cardiovascular mortality (%)	0.0	2.9	4.1
Stable CAD	0.0	1.4	1.4
ACS	0.0	4.0	6.1
Myocardial infarction	0.0	1.2	1.7
Stable CAD	0.0	0.0	0.0
ACS	0.0	2.0	3.0
TLR rate (%)	0.0	1.7	4.1
Stable CAD	0.0	0.0	1.4
ACS	0.0	3.0	6.1
Total mortality (%)	0.0	8.7	11.6
Stable CAD	0.0	4.1	5.5
ACS	0.0	12.1	16.2
TVR rate (%)	0	4.1	7.0
Stable CAD	0	0.0	1.4
ACS	0	7.1	11.1
Hospitalization for urgent revascularization (%)	0	2.9	6.4
Stable CAD	0	2.7	5.5
ACS	0	3.0	7.1
Stroke	3	2.9	4.1
BARC 2-5 bleeding	0	10.5	14.5
BARC 3-5 bleedings	2	2.3	3.5

- The overall MACE rate was low at 12 months (4.7%)
- ACS patients had significantly higher MACE rates vs stable CAD (7.1% vs 1.4%).
- At 24 months, the MACE rate was 8.1% (12.1% ASC and 2.7% stable CAD).
- Total mortality was higher among patients with ACS compared to patients with stable CAD (12.1% and 4.1%, respectively).
- CV mortality was low in the ACS group at 12 and 24 months (4.0% and 6.1%, respectively), and in stable CAD there was only one CV death at 12 months (1.4%).
- Importantly, there were no acute or subacute vessel closures despite omitting DAPT treatment after discharge. The rate of ischemia driven TLR was low in both groups: in the ACS group 3.0% and 0% in the stable CAD group at 12 months
- The rate of significant bleeding (BARC 2-5) was 10.5% at 12 months. Only 2.3% of the patients suffered severe bleeding (BARC 3-5).

Räsänen, A et al. Catheter Cardiovasc Interv. 2023;101:569–578.

Comparisons of DCB vs DES for the treatment of cancer patients presenting with STEMI



Among them, 48 patients were treated with DEB and 116 patients were treated with DES.

- Patients treated with DEB had a numerically lower rate of MACE than those treated with DES during the follow-up period (22.9% vs. 37.1%, HR 1.50, 95% CI [0.77, 2.92], p=0.23)
- Patients treated with DEB had a trend towards lower rate of major bleeding events than patients treated with DES (6.3% vs. 18.1%, HR 2.96, 95% CI [0.88, 9.92], p = 0.08)
- DEB tended to be more effective than DES in terms of reducing MACE rate for patients with active cancer, despite no statistical significance was not achieved (16.1% vs. 40.3%, HR 2.57, 95% CI [0.97, 6.57], p = 0.07)

Yang *et al. European Journal of Medical Research (2023) 28:334*

Single-Antiplatelet Treatment After Coronary Angioplasty With Drug-Coated Balloon

Retrospective analysis of 1,110 patients receiving DCB PCI for de novo lesions (2012–2021).

After 1year, the primary end point of MACE (and its components cardiac death, MI, TLR) was not significantly different between the 2 groups (10% versus 9%, *P*=0.78), but a reduction in the cumulative rate of 2 to 5 BARC bleedings was observed in the SAP group (9% versus 6%, *P*=0.04).

107 HBR/active bleeding patients remained, all on SAPT.

After adjusting for confounding factors through multivariate analysis bleeding diathesis, DAPT and anticoagulant use were predictors of BARC bleedings, whereas bleeding diathesis and acute coronary syndromes were predictors of major adverse cardiac events.

Compared 1-year outcomes between:
The SAPT HBR cohort (n=107)
All DCB-treated patients (n=1110)

Thrombotic event rates were not significantly different comparing a SAP regimen after DCB with standard antiplatelet regimen, and BARC bleedings were found to be lower after 12 months

Bernardo Cortese; Patrick W. Serruys, *J Am Heart Assoc.* 2023;12

PICCOLETO IV-Epic RCT

Trial name & number	Single vs. dual antiplatelet therapy in **elderly OR HBR** patients undergoing PCI with drug-coated balloon. PICCOLETO IV-EPIC study. NCT: Pending.
Study Sponsors	Fondazione Ricerca e Innovazione Cardiovascolare, Milano, Italy Fundación Epic, León, Spain
Steering Commitee	B. Cortese, J. M. De la Torre Hernández, A. Pérez de Prado, S. De Servi
Study device	Drug-coated balloon: Essential Pro
Aims	To observe and evaluate the rate of ischemic and bleeding adverse events of a single antiplatelet regimen (SAPT) since the time of PCI with latest generation DCB in an elderly population.

Conclusions

Take home messages

DCB-only percutaneous coronary intervention (PCI) is the concept of treating coronary stenoses while limiting the need for permanent or semipermanent implants to those lesions at high risk for acute vessel closure or unfavourable long-term results.

Potentially, every PCI should aim at using the DCB-only strategy, which implies a similar approach for every lesion preparation.

Although their efficacy and safety have been proved for both instent restenosis (ISR) and native small-vessel disease, there are other emerging indications (e.g., bifurcation lesions, large-vessel disease, and high bleeding risk).

DCB is a very attractive proposition for all patients with stable coronary disease identified as being at a high risk of bleeding

Bernardo Cortese; Patrick W. Serruys, *J Am Heart Assoc.* 2023;12

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30th Anniversary
TCTAP 2025
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Thank You for attention

F. Fouladvand
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CVRF