

PCI in High Bleeding Risk Patients

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Disclosure

▶ Grant support

- Korean Society of Interventional Cardiology
- Ministry of Health & Welfare, Republic of Korea
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- Abbott Vascular, Boston Scientific, Biotronik, Biometrics, and Medtronic

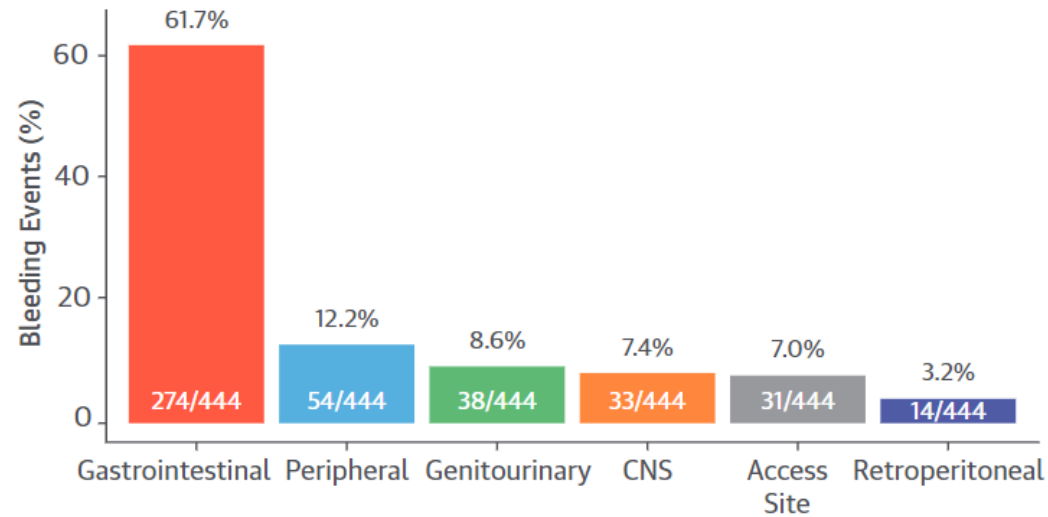
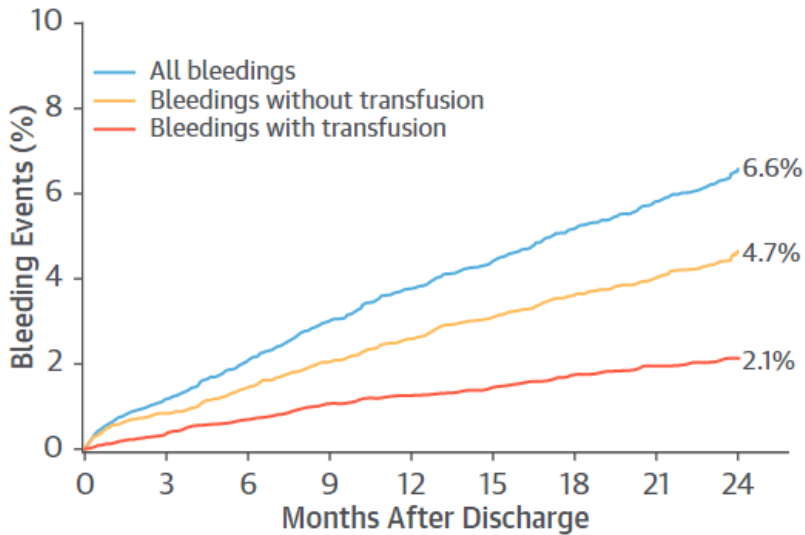
▶ Consulting Fees/Honoraria

- Abbott Vascular, Astra Zeneca, Biotronik, Biometrics, Daiichi Sankyo, Pfizer, and Sanofi-Aventis



Incidence and site of post-discharge bleeding (PDB)

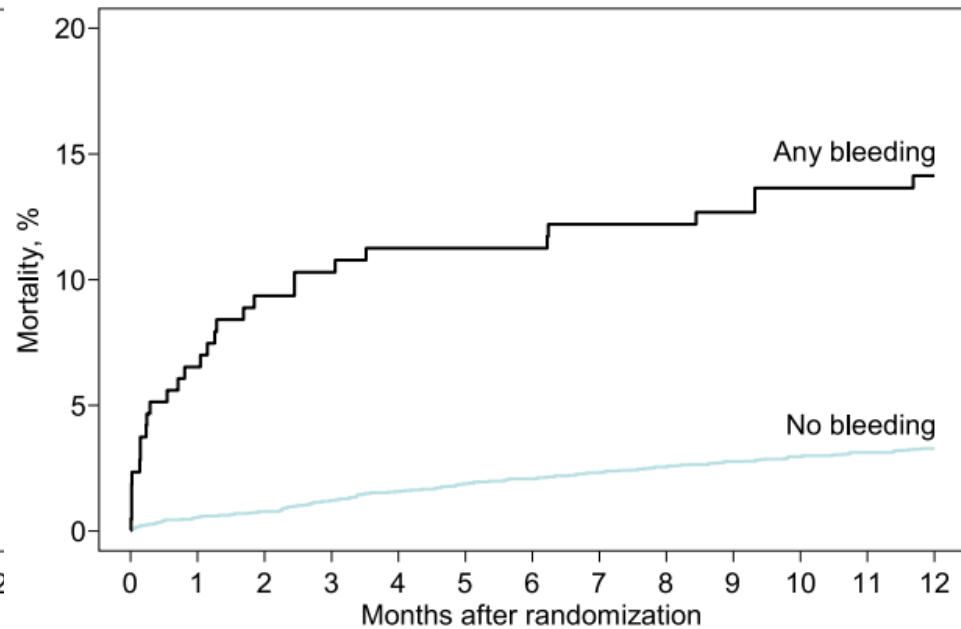
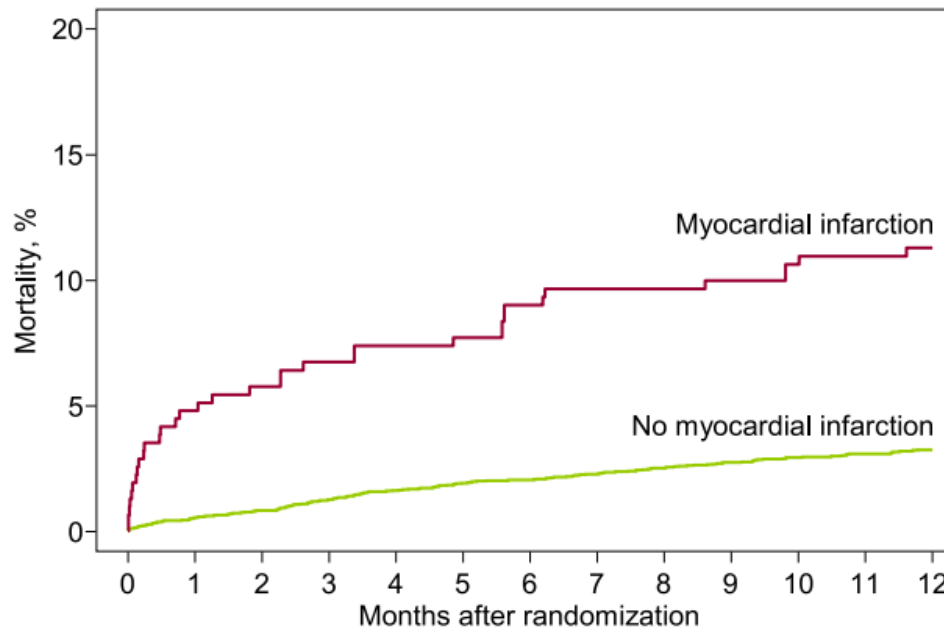
ADAPT-DES study





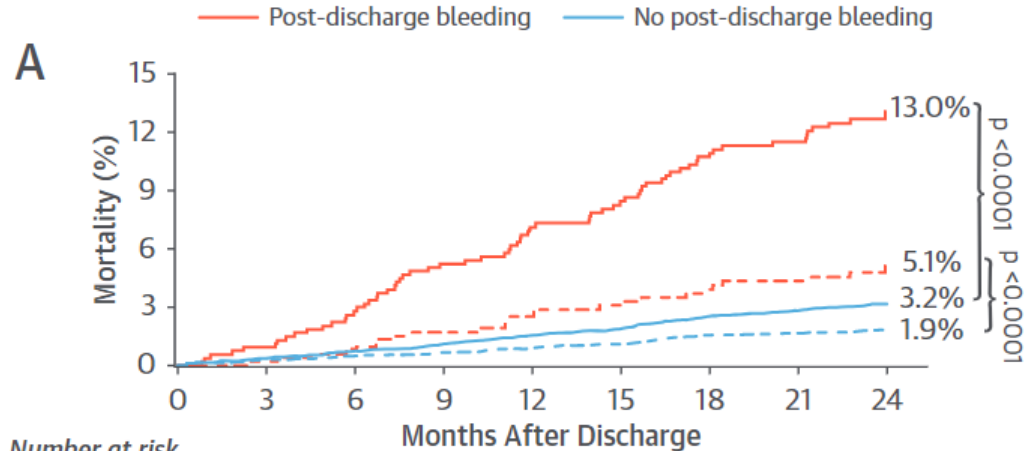
Periprocedural (<30 days) Bleeding and 1-Year Outcome after PCI

Pooled analysis: ISAR-REACT, -SWEET, -SMART-2, and -REACT-2



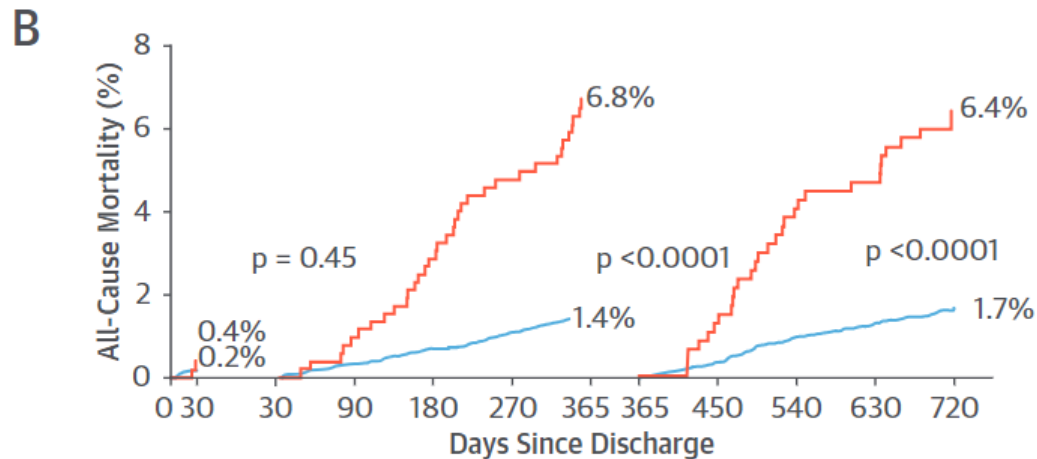


All-Cause and Cardiac Mortality According to PDB



Number at risk

	PDB	535	529	520	506	492	480	467	461	289
	No PDB	8,042	7,840	7,795	7,756	7,631	7,446	7,369	7,306	4,739



Number at risk

	PDB	535	532	529	520	506	489	480	467	461	265
	No PDB	8,042	7,935	7,840	7,795	7,756	7,619	7,446	7,369	7,306	4,407

Predictors of PDB Within 2 Years



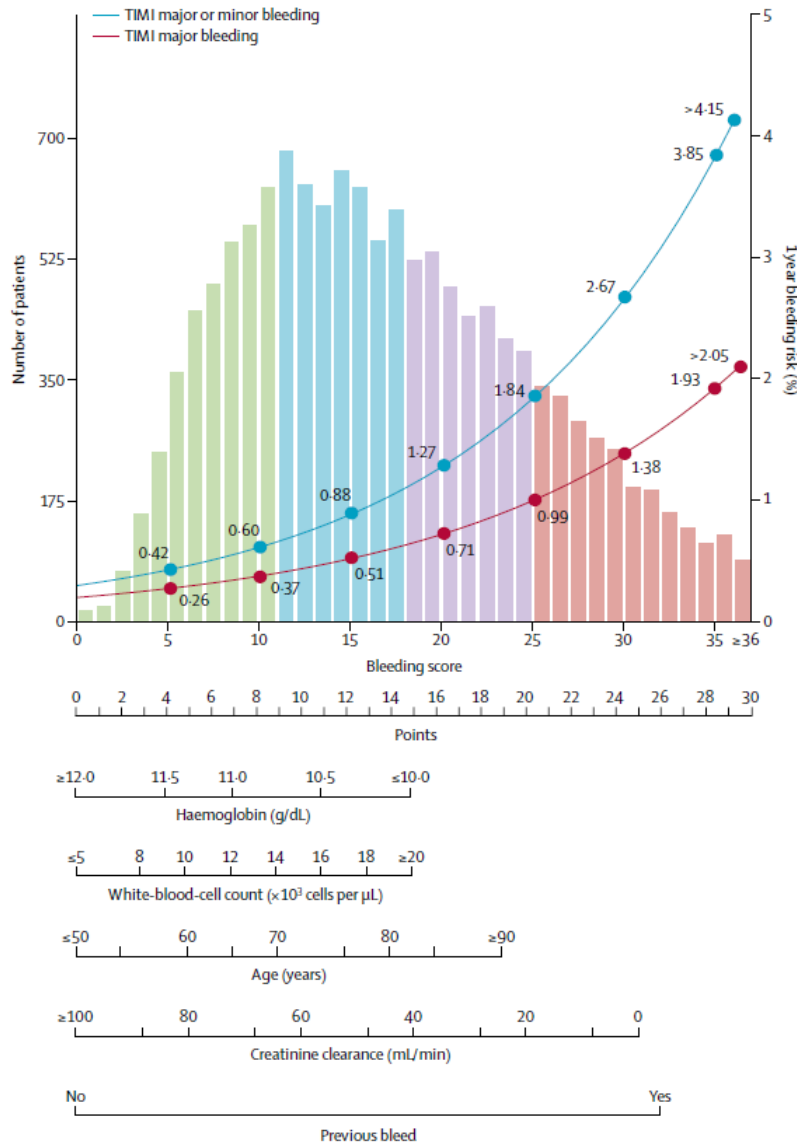
ADAPT-DES study

TABLE 2 Independent Predictors of PDB Within 2 Years

Variable*	HR (95% CI)	p Value
Age (per yr increase)	1.02 (1.01-1.03)	<0.0001
Warfarin, at discharge	2.31 (1.78-2.99)	<0.0001
Peripheral artery disease	1.57 (1.25-1.98)	0.0001
Calcified lesion	1.25 (1.05-1.50)	0.01
Bifurcation lesion	1.32 (1.06-1.64)	0.01
Platelet reactivity units (per 10-unit decrease)	1.01 (1.01-1.02)	0.002
Baseline hemoglobin (per g/dl decrease)	1.28 (1.22-1.37)	<0.0001

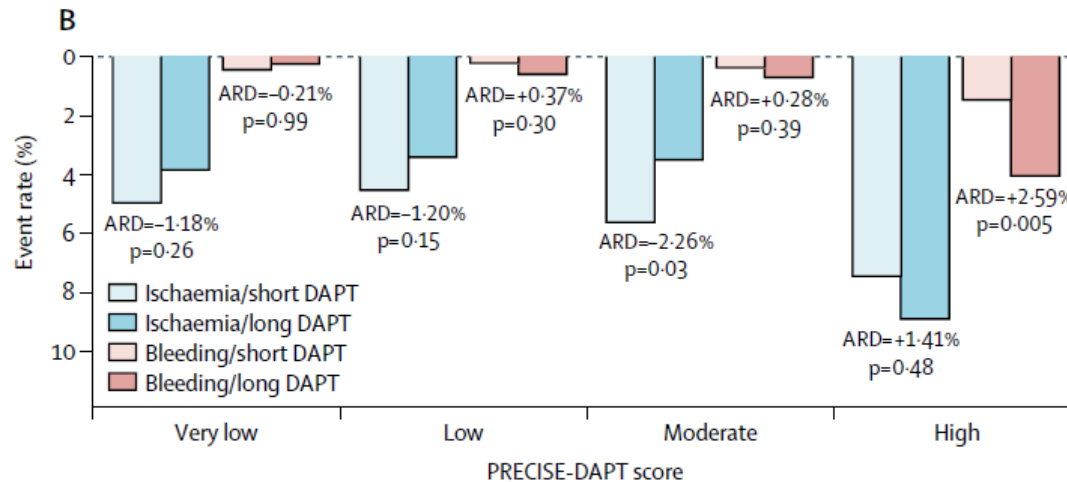
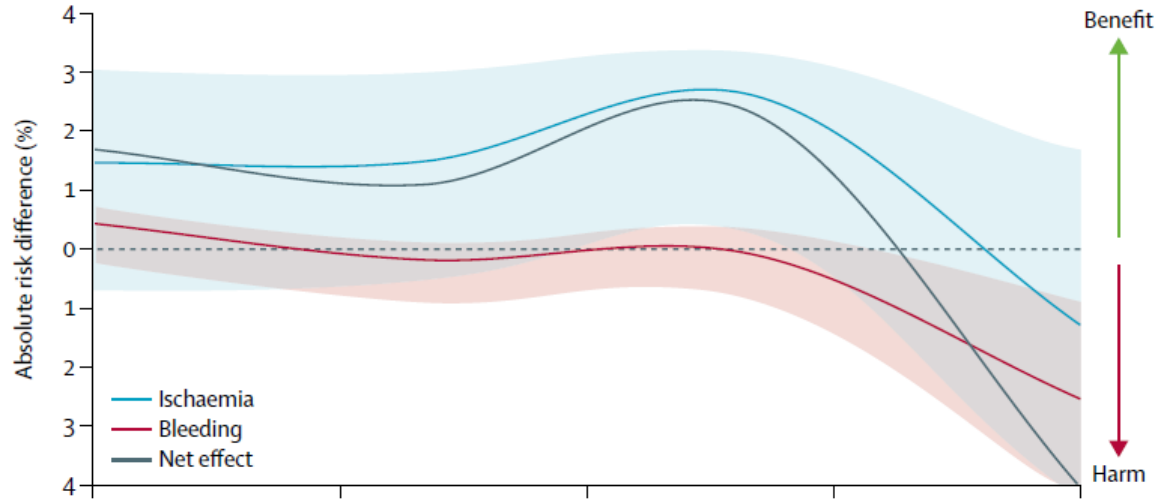


PRECISE-DAPT score





PRECISE-DAPT score



high risk: score ≥ 25

Selection of stents: DES vs. BMS



- ▶ **LEADERS FREE trial**
 - BioFreedom biolimus A9 drug-coated stent vs. BMS
 - High bleeding risk patients

- ▶ **ZEUS trial**
 - Zotarolimus-eluting Endeavor sprint stent vs. BMS
 - Uncertain candidates for DES including HBR patients

- ▶ **SENIOR trial**
 - Synergy bioabsorbable-polymer everolimus-eluting stent vs. BMS
 - 75 years or older

LEADERS FREE: study design



Prospective, double-blind randomized (1:1) trial
2466 High bleeding risk (HBR) PCI patients

BioFreedom™
DCS

vs.

Gazelle™
BMS

DAPT mandated for 1 month only, followed by long-term SAPT

- **Primary safety endpoint:**
Composite of cardiac death, MI, definite / probable stent thrombosis at 1 year (non-inferiority then superiority)
- **Primary efficacy endpoint:**
Clinically-driven TLR at 1 year (superiority)

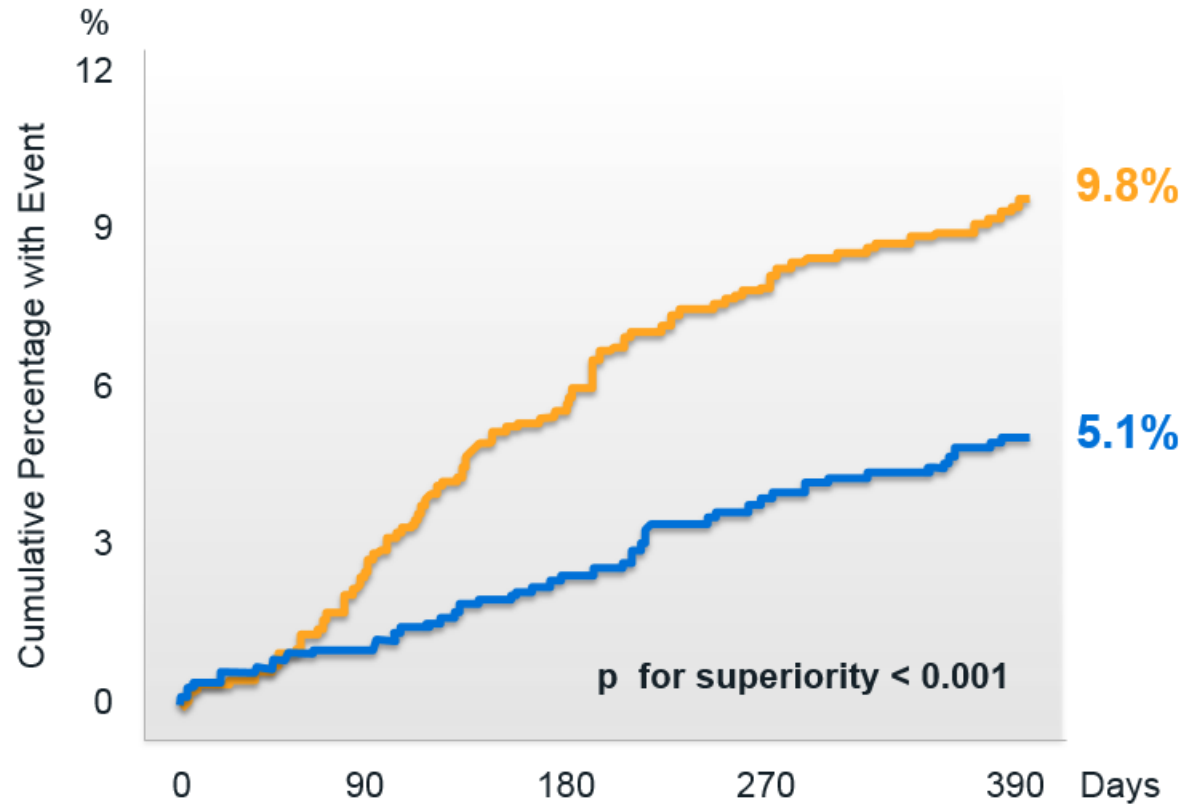
LEADERS FREE: Inclusion Criteria (One or More)



- ▶ Age \geq 75 years
- ▶ OAC planned after PCI
- ▶ Baseline Hb $<$ 11g / dl or transfusion during prior 4 weeks
- ▶ Planned major surgery (within next year)
- ▶ Cancer diagnosed or treated \leq 3 years
- ▶ Creatinine clearance $<$ 40 ml / min
- ▶ Hospital admission for bleeding during past year
- ▶ Thrombocytopenia ($<$ 100.000 / mm³)
- ▶ Any prior intra-cerebral bleed
- ▶ Any stroke during the past year
- ▶ Severe liver disease
- ▶ NSAID or steroids planned after PCI
- ▶ Anticipated poor DAPT compliance for other medical reason



LEADERS FREE: Primary Efficacy Endpoint (Clinically-Driven TLR)

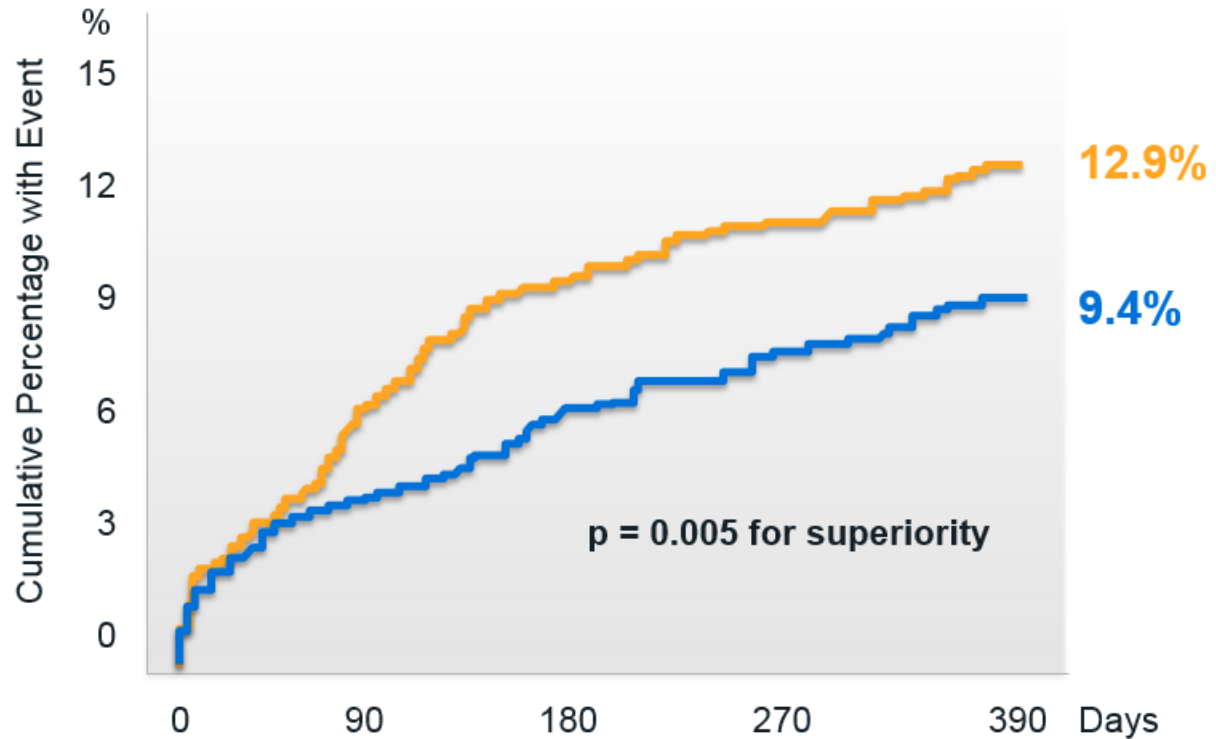


Number at Risk

DCS	1221	1167	1130	1098	1053
BMS	1211	1131	1072	1034	984



LEADERS FREE: Primary Safety Endpoint (Cardiac Death, MI, ST)

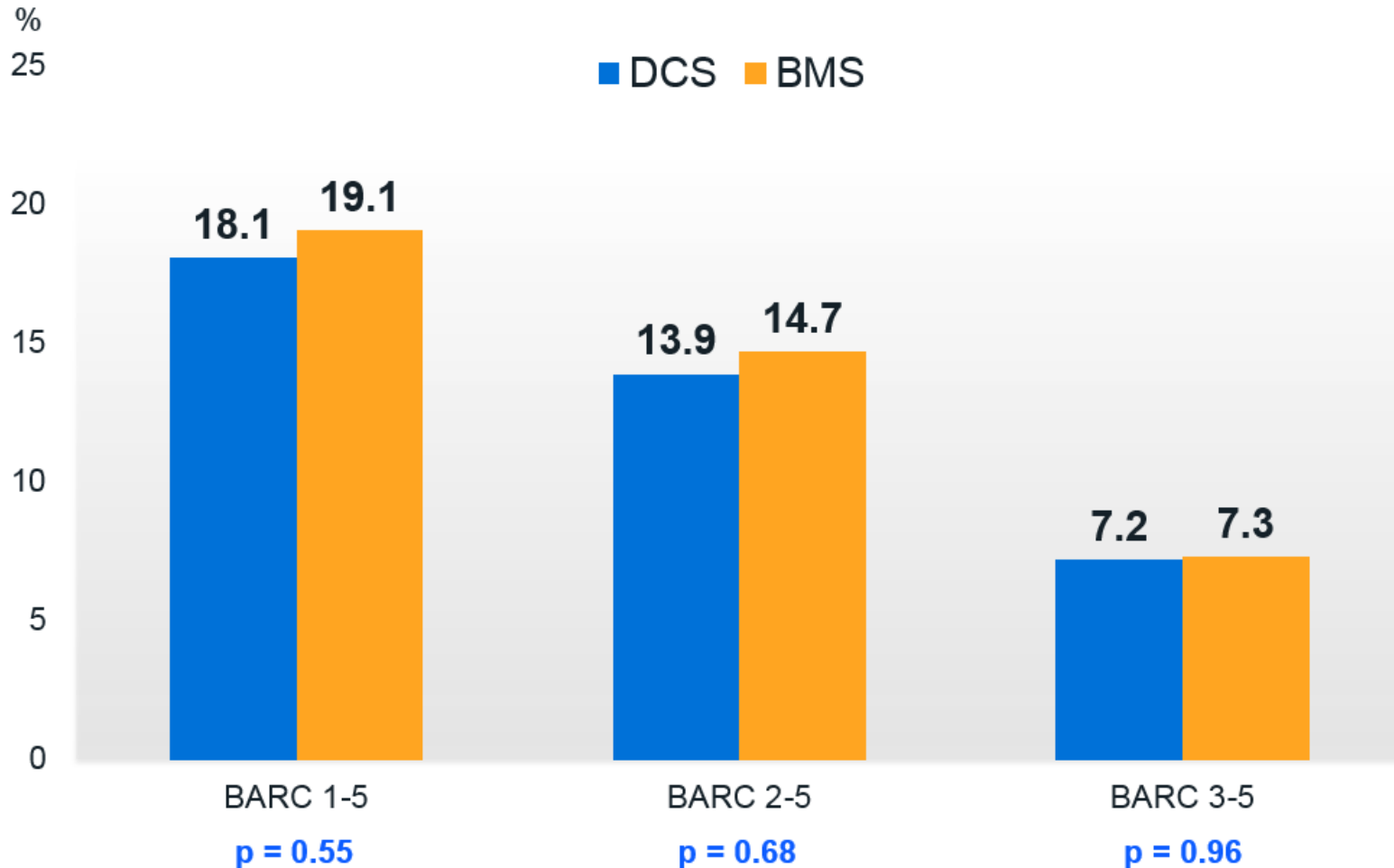


Number at Risk

	0	90	180	270	390
DCS	1221	1146	1105	1081	1045
BMS	1211	1115	1066	1037	1000



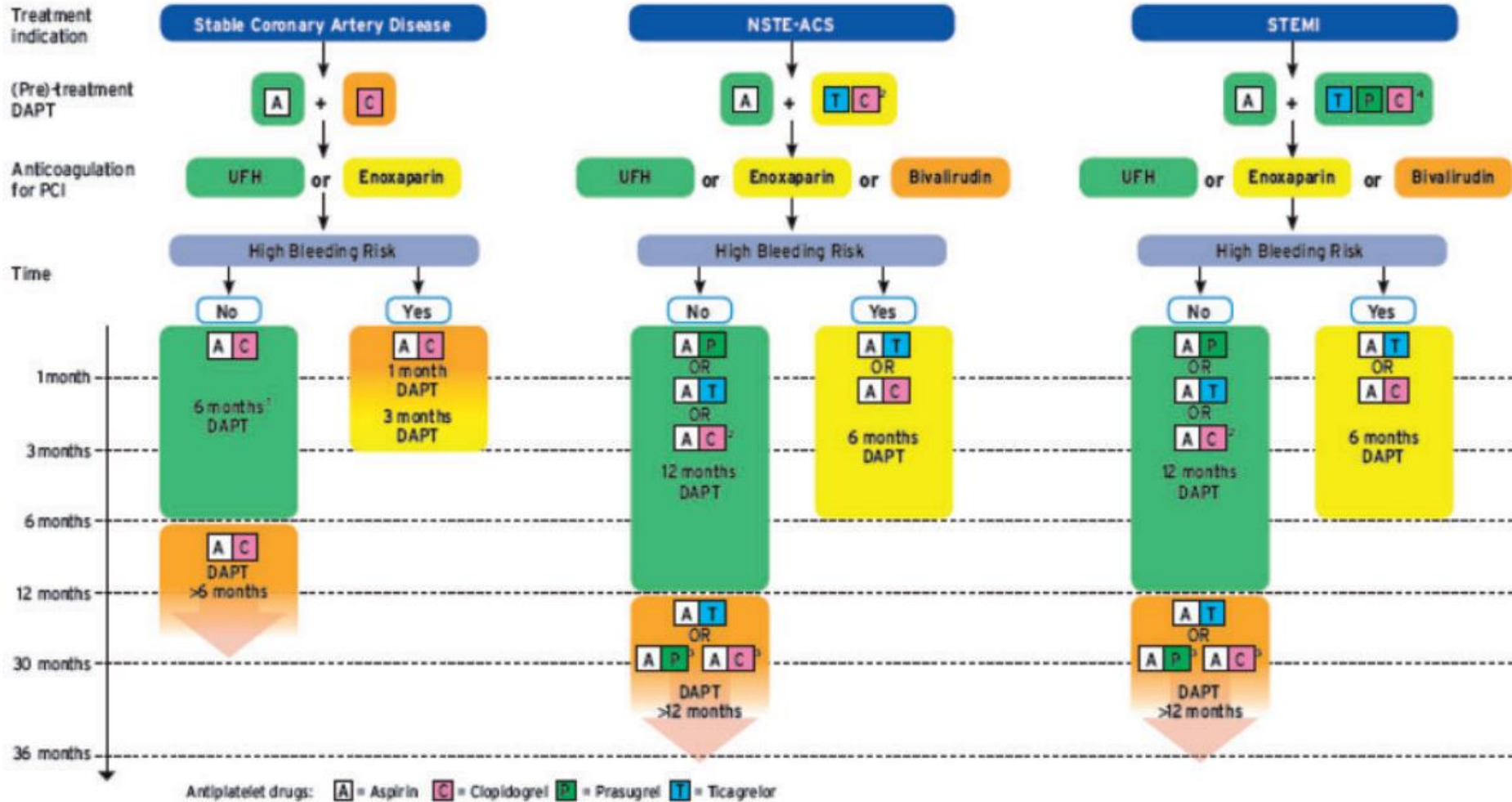
LEADERS FREE: Bleeding





2018 ESC/EACTS Guidelines on myocardial revascularization

Antithrombotic Treatment in Patients Undergoing Percutaneous Coronary Intervention



On-going trials on HBR patients



- ▶ OnyxOne
 - Onyx vs. Biofreedom with 1 month DAPT

- ▶ MASTER-DAPT
 - One-month vs. 5-month or longer DAPT with Ultimaster family

- ▶ Xience28
 - One arm registry of Xience family

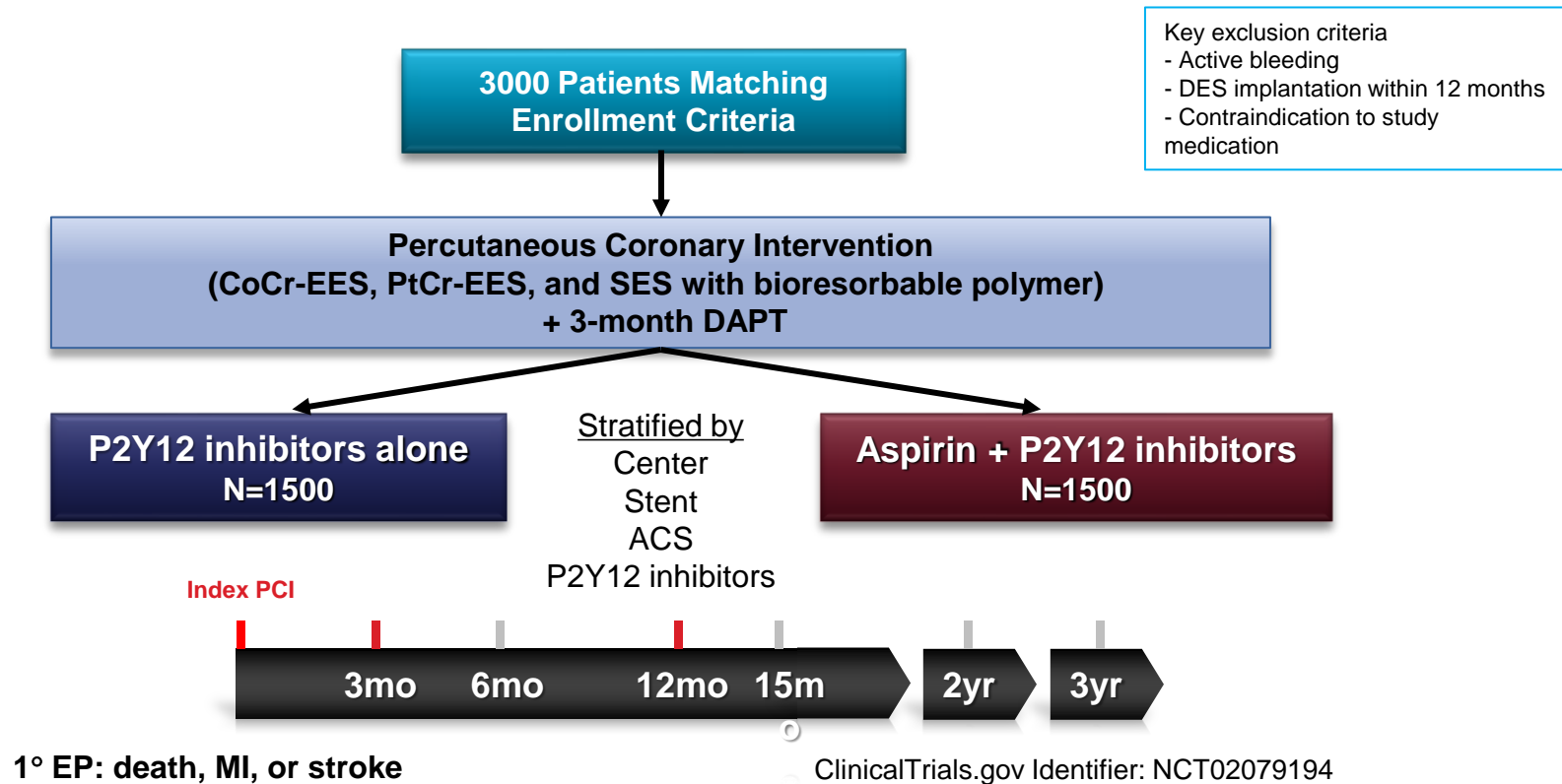
- ▶ And so on

SMART-CHOICE trial



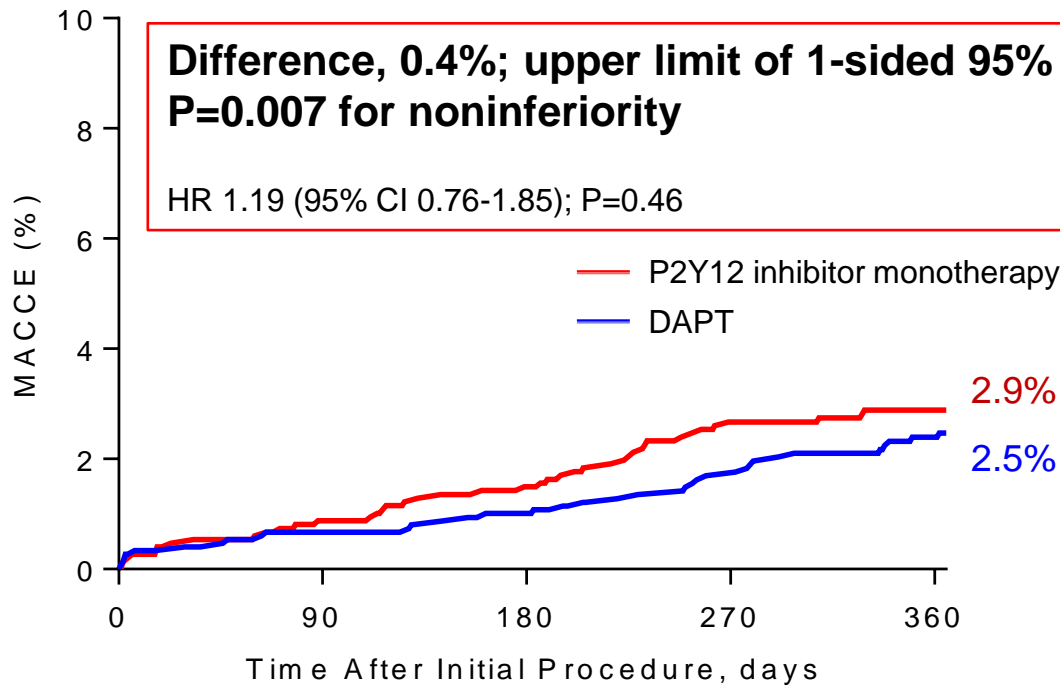
Comparison between P2Y12 Antagonist Monotherapy and Dual Antiplatelet Therapy in Patients Undergoing Implantation of Coronary Drug-Eluting Stents

A prospective, multicenter, randomized, open-label, noninferiority trial





Primary end point (MACCE)



2.9%
2.5%

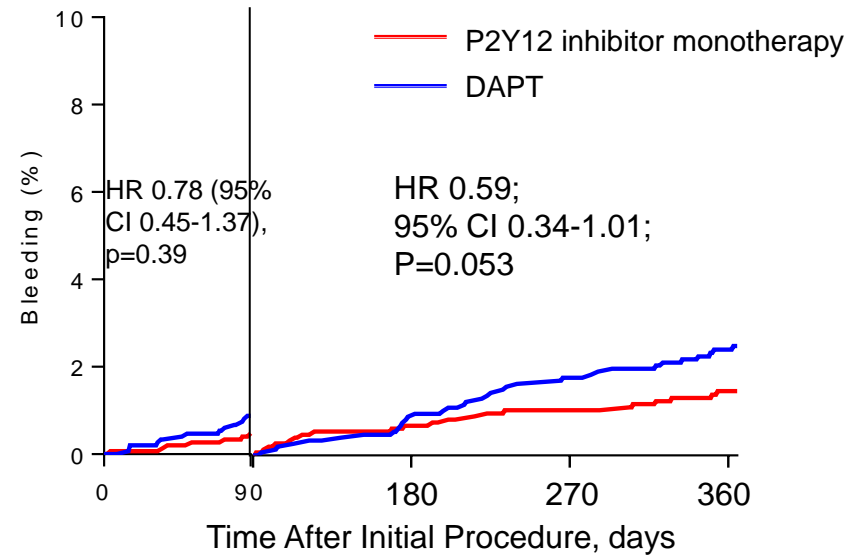
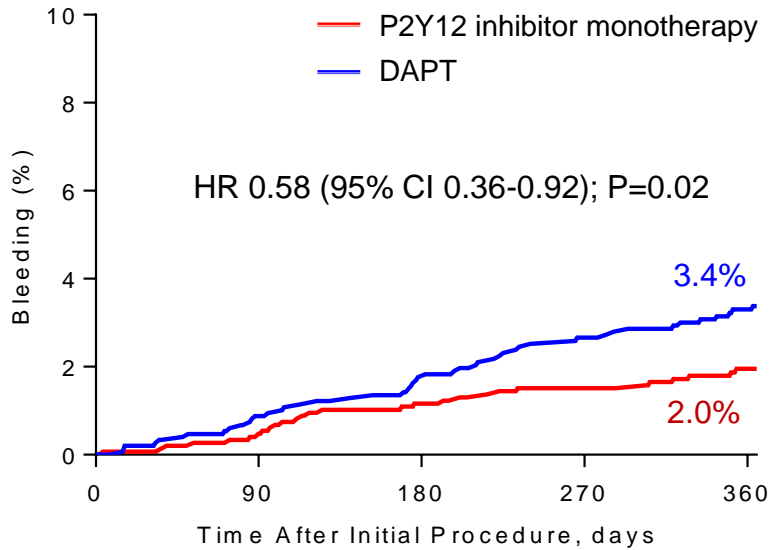
No. at risk

DAPT	1498	1471	1454	1436	1220
P2Y12 inhibitor	1495	1456	1430	1402	1202

* MACCE = A composite of all-cause death, myocardial infarction, or stroke



Bleeding (BARC 2-5)



No. at risk	0	90	180	270	360
DAPT	1498	1461	1435	1413	1197
P2Y12 inhibitor	1495	1456	1425	1400	1198

No. at risk	0	90	180	270	360
DAPT	1498	1461	1435	1413	1197
P2Y12 inhibitor	1495	1456	1425	1400	1198



Summary

- ▶ Post-discharge bleeding is not uncommon and has a strong relationship with subsequent all-cause mortality comparable to or greater than that of MI.
- ▶ To identify patients with HBR is of great importance. PRECISE-DAPT score is a simple, but standardized tool.
- ▶ DESs have shown superior efficacy and comparable safety compared with BMS in HBP patients.
- ▶ Short duration of DAPT needs to be considered in this population.
- ▶ P2Y12 inhibitor monotherapy after short duration of DAPT can be another option for HBR patients.

감사합니다.
Thank you for your attention.

