

High bleeding risk patients: from clinical evidence to routine practice

Singapore, January 25, 2018

Pioneering the New World of HBR Patients



*Philip Urban MD
Hôpital de la Tour
Geneva Switzerland*

Pioneering the New World of HBR Patients

- **A working definition of HBR patients**
- Bleeding avoidance strategies
 - Vascular access
 - Choice of stent
 - Antithrombotic medication

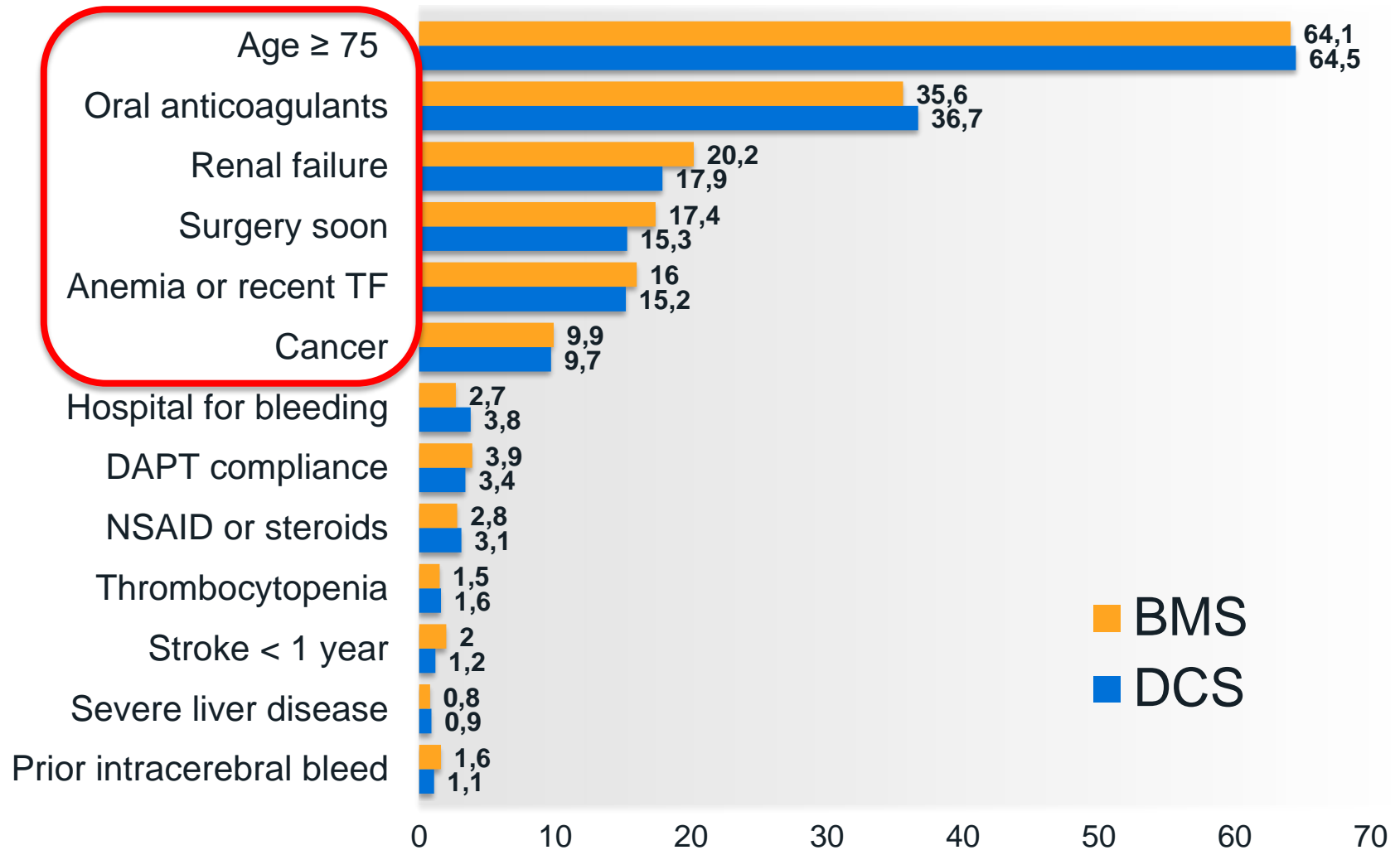
The « HBR »

Planned surgery



Shortened
DAPT

Inclusion Criteria Applied (1.7 criteria / patient)



Who are HBR patient?

Trial inclusion criteria

	LEADERS FREE	ZEUS HBR*	MASTER DAPT	EVOLVE SHORT DAPT	XIENCE 90 SHORT DAPT	ONYX ONE	SENIOR	COBRA REDUCE
Age \geq 75 (or 80*)	✓	✓	✓	✓	✓	✓	✓	
OAC	✓	✓	✓	✓	✓	✓		✓
Renal failure	✓			✓	✓	✓		
Surgery soon	✓					✓		
Anaemia or TF	✓	✓	✓		✓	✓		
Hospital for bleeding	✓	✓	✓			✓		
Actionable bleed			✓	✓	✓			
Thrombocytopenia	✓	✓	✓	✓	✓	✓		
Recent cancer	✓		✓			✓		
Stroke/ICH	✓		✓	✓	✓	✓		
Liver disease	✓					✓		
NSAID	✓	✓	✓			✓		
PRECISE DAPT >25			✓					
Experimental DAPT	1 month	1 month	1 month	3 months	3 months	1 month	1or 6 mths	2 weeks

Pioneering the New World of HBR Patients

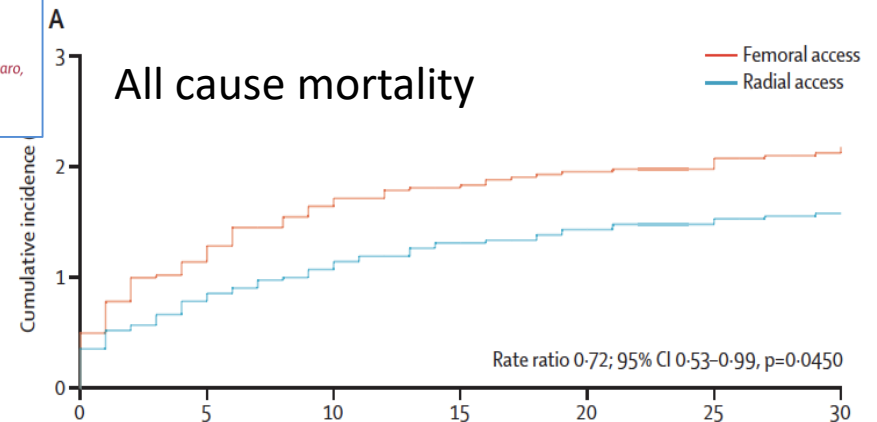
- A working definition of HBR patients
- **Bleeding avoidance strategies**
 - **Vascular access**
 - Choice of stent
 - Antithrombotic medication

Radial versus femoral access in patients with acute coronary syndromes undergoing invasive management: a randomised multicentre trial

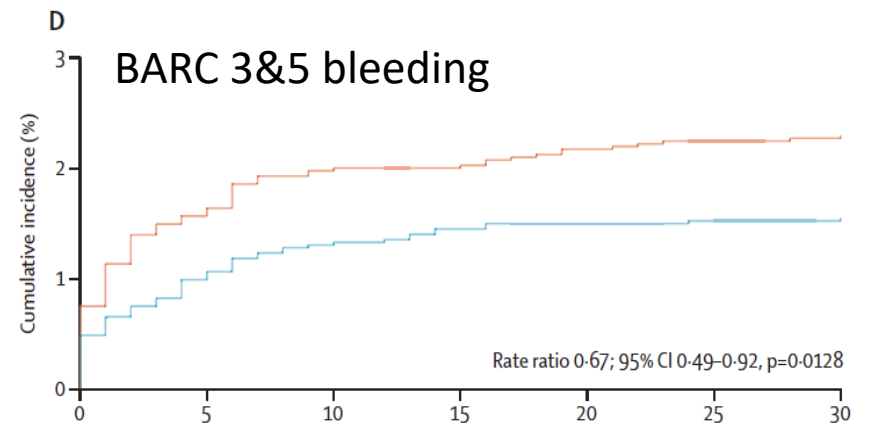
Marco Valgimigli, Andrea Gagnor, Paolo Calabró, Enrico Frigoli, Sergio Leonardi, Tiziana Zaro, Paolo Rubartelli, Carlo Briguori, Giuseppe Andò, Alessandra Repetto, Ugo Limbruno, Bernardo Cortese, Paolo Sganzerla, Alessandro Lupi, Mario Galli, Salvatore Colangelo, Salvatore Ierna, Arturo Ausiello, Patrizia Presbitero, Gennaro Sardella, Ferdinando Varbella, Giovanni Esposito, Andrea Santarelli, Simone Tresoldi, Marco Nazzaro, Antonio Zingarelli, Nicoletta de Cesare, Stefano Rigattieri, Paolo Tosi, Cataldo Palmieri, Salvatore Brugaletta, Sunil V Rao, Dik Heg, Martina Rothenbühler, Pascal Vranckx, Peter Jüni, for the MATRIX Investigators*

Lancet 2015; 385: 2465-76
MATRIX

- 8404 patients with ACS & PCI
- Randomized to radial vs. femoral access
- Co-primary endpoints @ 30 days:
 - MACE (non-significant at α of 0.025)
 - NACE (MACE+maj.bleeding) (0.83, 95% CI 0.73–0.96; $p=0.0092$)



Number at risk	0	5	10	15	20	25	30
Femoral access	4207	4146	4122	4115	4109	4108	4102
Radial access	4197	4155	4138	4128	4123	4121	4115



Number at risk	0	5	10	15	20	25	30
Femoral access	4207	4087	4051	4046	4034	4031	4025
Radial access	4197	4124	4095	4080	4074	4071	4065

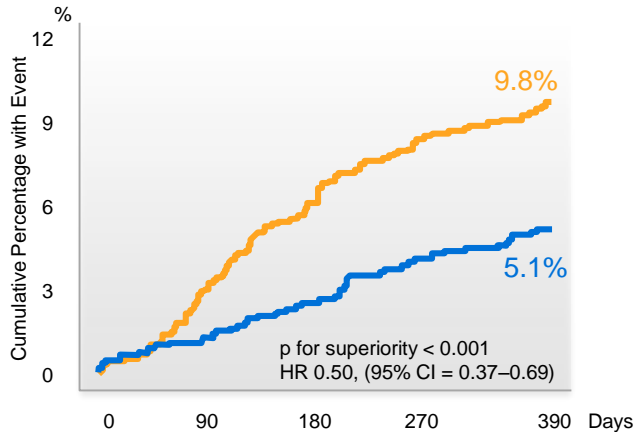
Pioneering the New World of HBR Patients

- A working definition of HBR patients
- **Bleeding avoidance strategies**
 - Vascular access
 - **Choice of stent**
 - Antithrombotic medication

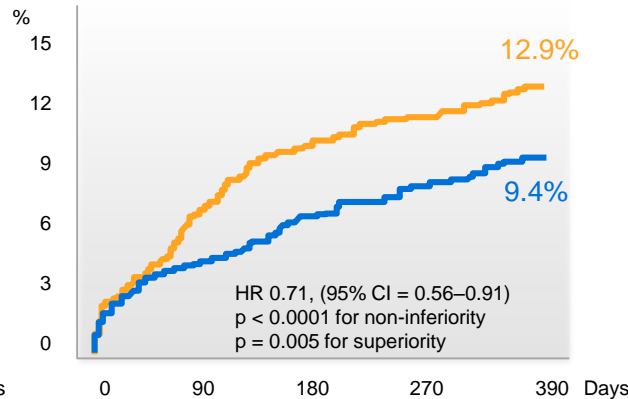
Primary Endpoints and Major Bleeding at 1 Year

DCS BMS

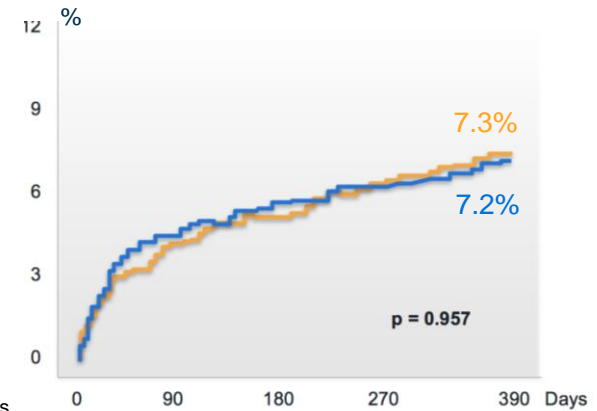
Efficacy (cd-TLR)



Safety (cardiac death, MI, ST)



Bleeding (BARC 3-5)



2466 High bleeding risk (HBR) PCI patients

BioFreedom™
DCS

vs.

Gazelle™
BMS

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

2nd G DES: 14 trials of short DAPT (3 months or less)

Trial	stent	type	limus kinetics	patients	experimental arm DAPT	control arm	Status November 2017
SENIOR (1)	Synergy EES	2 nd G biodegradable polymer	slow	1200 elderly (≥ 75)	1 month or 6 months (operator discretion)	BMS & same DAPT	DES superior to BMS for MACE (efficacy + safety combined)
LEADERSFREE II	BioFreedom DCS	polymer-free	fast	1200 HBR	1 month	BMS arm of LEADERS FREE	follow-up
LEADERS FREE III	CoCr BioFreedom	Polymer-free	fast	370 HBR	1 month	DCS arm of LEADERS FREE	enrolling
YONSEI UNIVERSITY	BioFreedom DCS	polymer-free	fast	3020 low risk SCAD	1 month	DES & 6-12 months DAPT	enrolling
ISAR DAPT	Coroflex ISAR	polymer-free matrix	slow	906 low risk SCAD	3 months	6 months DAPT	enrolling
ReCre8	Cre8 SES	polymer-free	slow	1532 all-comers	SCAD 1 month ACS 12 months	R-ZES same DAPT	enrolling
EVOLVE SHORT DAPT	Synergy EES	2 nd G BD polymer	slow	2000 HBR	3 months	single arm trial	enrolling
MASTER DAPT	Ultimaster SES	2 nd G BD polymer	slow	4300 HBR	1 month	guidelines	enrolling
HOST-IDEA	Orsiro SES vs. Coroflex ISAR	2 nd G BD polymer vs. polymer-free matrix	slow slow	2132 SCAD (no OAC)	3 months	1 year DAPT	enrolling
STOPDAPT-2	Xience EES	2 nd G permanent polymer	slow	3000 low/med risk success PCI	1 month	1 year DAPT	enrolling
COBRA-REDUCE	Cobra PzF	Polyzene-F nanocoating	na	840 on AVK or NOAC	2 weeks	EES or R-ZES & 6 months DAPT	enrolling
POEM	Synergy EES	2 nd G BD polymer	slow	1000 HBR	1 month	single arm trial	enrolling
XIENCE 90 (Xience Short DAPT)	Xience EES	Permanent polymer	Slow	2000 HBR	3 months	Single arm trial	enrolling
ONYX ONE	Resolute Onyx DES vs. BioFreedom DCS	Permanent polymer vs. Polymer-free	Slow vs. Fast	2000 HBR	1 month	1 month	planned

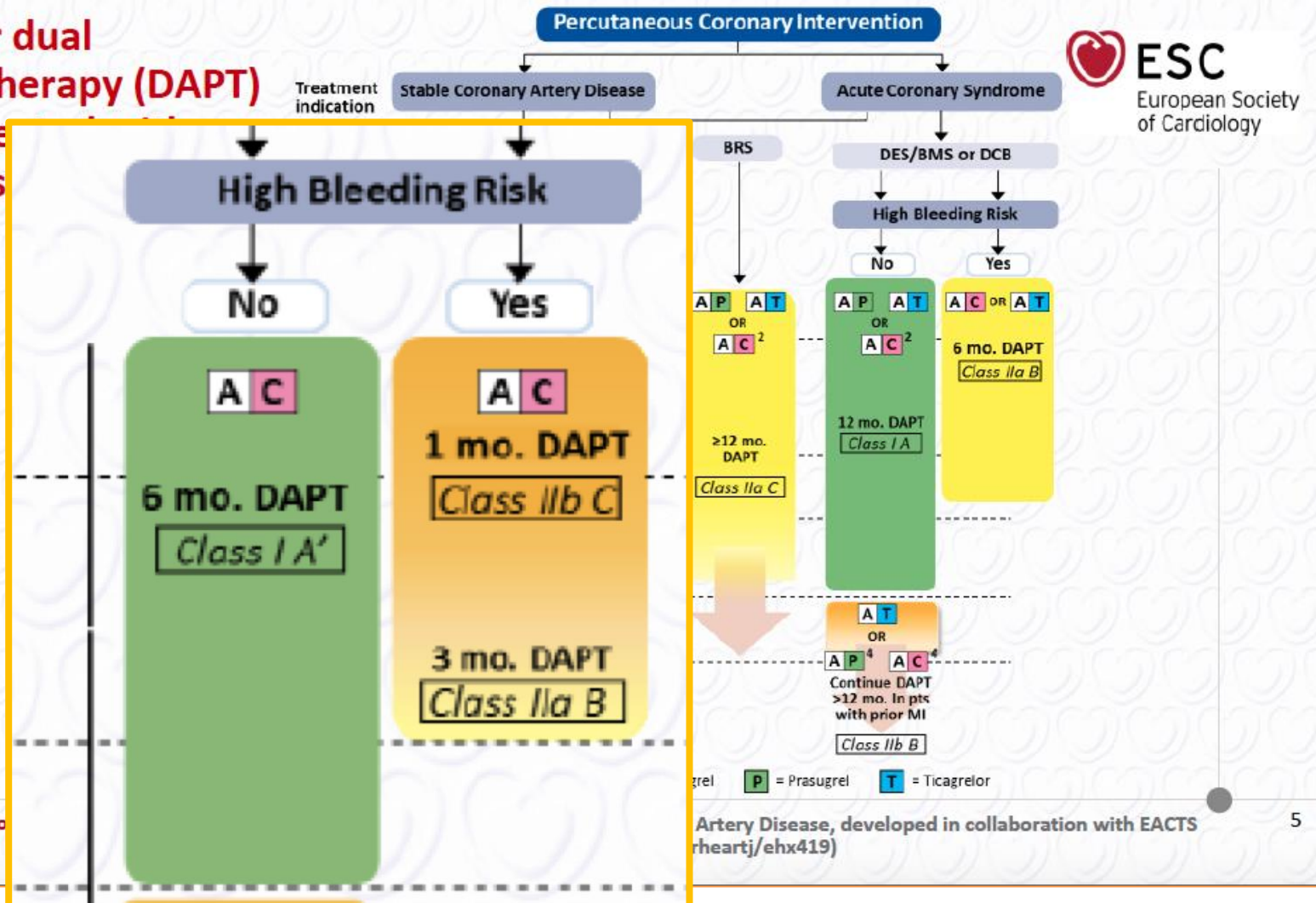
Pioneering the New World of HBR Patients

- A working definition of HBR patients
- **Bleeding avoidance strategies**
 - Vascular access
 - Choice of stent
 - **Antithrombotic medication**

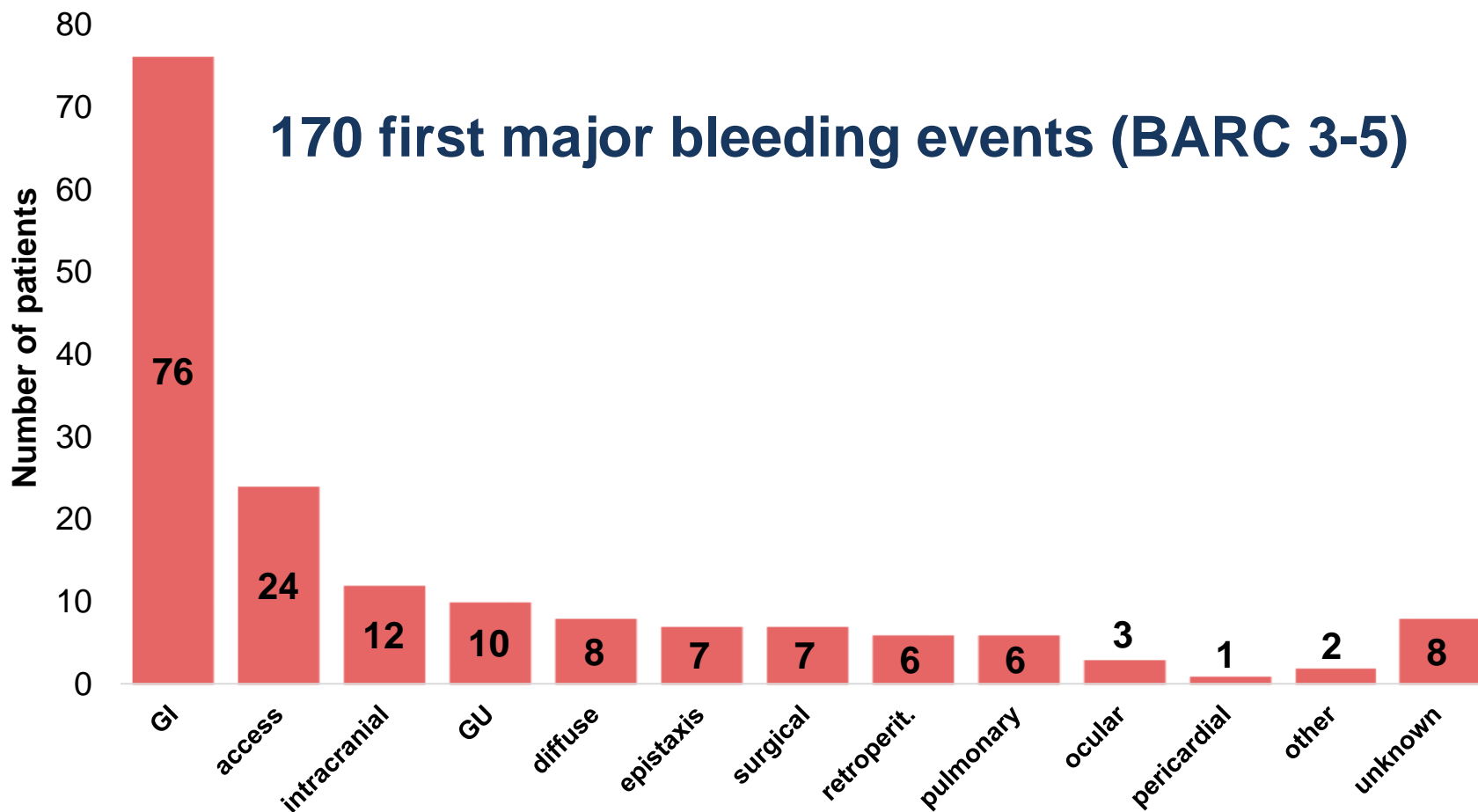
2017 ESC Focused Update on DAPT in Coronary Artery Disease

(European Heart Journal 2017 - doi:10.1093/eurheartj/ehx419)

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



Location of Major Bleeding



Conclusions

The realisation that HBR patients require specific therapeutic measures is having a major impact on PCI practice and guidelines:

- ✓ Radial access whenever possible
- ✓ BMS no longer recommended
- ✓ Default approach: shorten DAPT to 3 months (DES) or 1 month (DCS)
- ✓ Prescribe PPI liberally
- ✓ Every HBR patient is different (presentation, target lesion, procedure), so remember to use your clinical judgment!

Thank you

PCR