

Potential conflicts of interest

Speaker's name: Thomas Cuisset, MD, PhD

X I have the following potential conflicts of interest to report:

x Consulting: Astra Zeneca, SANOFI

Employment in industry

Stockholder of a healthcare company

Owner of a healthcare company

x Others: Lecture Fee

Abbott Vascular, Astra Zeneca, Boston Scientific, Medtronic, SANOFI, Terumo

I do not have any potential conflict of interest

Qui est à haut risque hémorragique ?



Thomas CUISSET, Marseille, France
Congrès du GRCI, Décembre 2018

Qui est à haut risque hémorragique ?

Who and two other questions !

1. What is « High bleeding Risk » ?
2. How HBR should modify clinical decisions ?

What is « High Bleeding Risk » in PCI patients ?

Site of Bleeding: Access-site (PCI) vs Non Access Site (DAPT)

Timing of Bleeding: In Hospital vs Post Discharge

Severity of Bleeding: BARC 2 vs BARC 3-5

How HBR should modify clinical decisions ?

Optimal management of HBR situations ?



Who ? = Identification of HBR Patients

Scores versus clinical judgment ?

Main criteria: Elderly, prior bleeding, OAC, anemia, cancer and planned surgery

Different patients in the same “HBR box”



→ Individualized treatment



Who ? = Identification of HBR Patients

2 Challenges:

Patients very often excluded from RCT

→ **Evidence ?**

Many of these patients are also High-ischemic risk ones

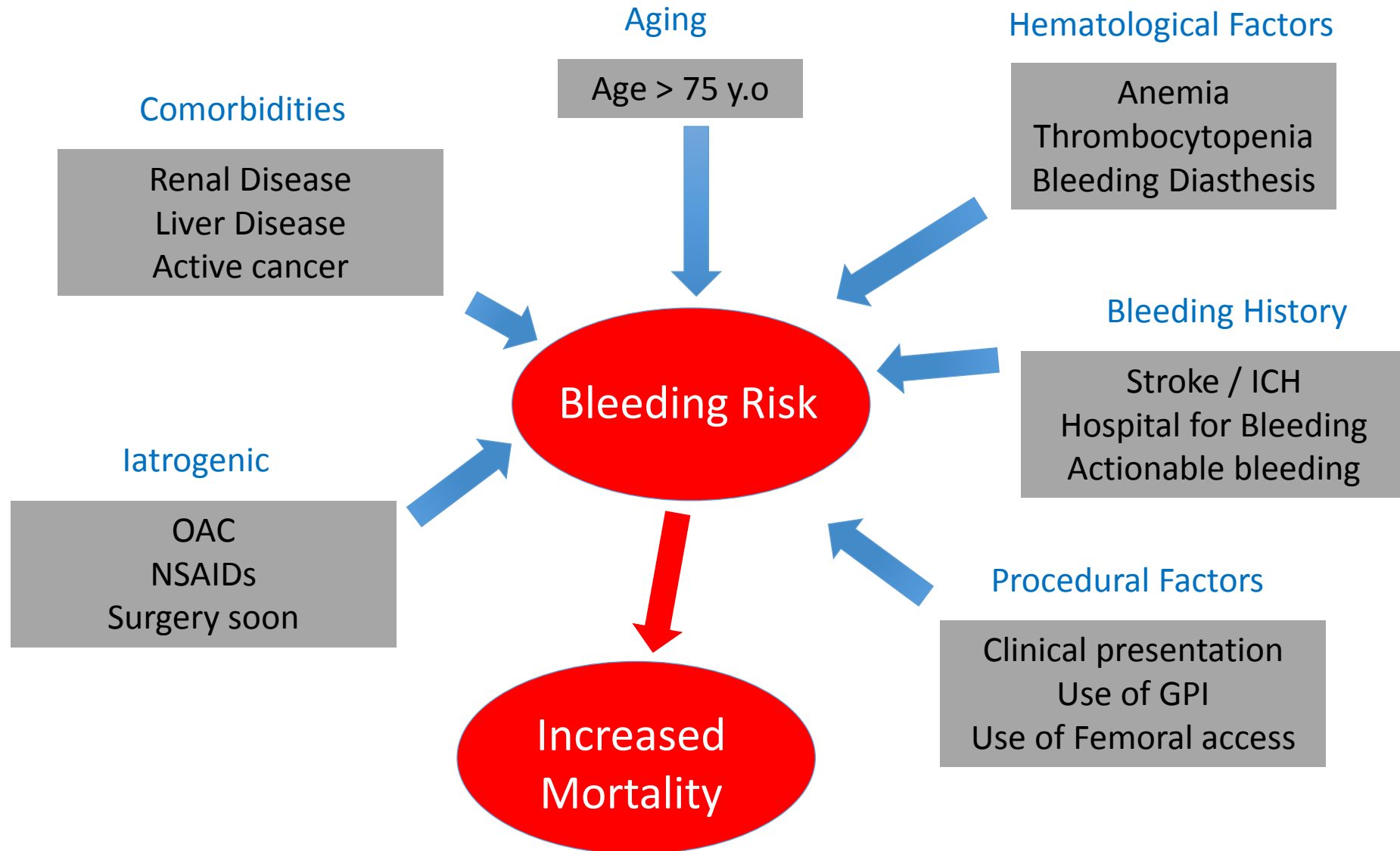
→ **Management ?**

Identification of HBR Patients: Scores






















































Long Term Scores in PCI patients: Characteristics

	BleeMACS	DAPT	PARIS	PRECISE-DAPT
Year of publication	2018	2016	2016	2017
Patients, n	15401	11648	4190	14963
Patient population	ACS undergoing PCI	Stable event-free 12 months after PCI	stable and unstable undergoing PCI	Stable and unstable undergoing PCI
Bleeding outcome	Serious spontaneous bleeding at 1 year	Major bleeding between 12 and 30 months after PCI	Major bleeding over 2 years	Major or minor bleeding out-of-hospital (≥ 7 days after PCI), median follow-up 552 days
Bleeding def	Protocol definition	GUSTO definition	BARC definition	TIMI definition
External validation (c-statistic)	AUC=0.65 ACS_PCI and 0.63 ACS	AUC: 0.64 (bleeding) AUC:0.64 (ischemia)	AUC: 0.64 (bleeding)	AUC: 0.66 and 0.70

Who ? = Identification of HBR Patients

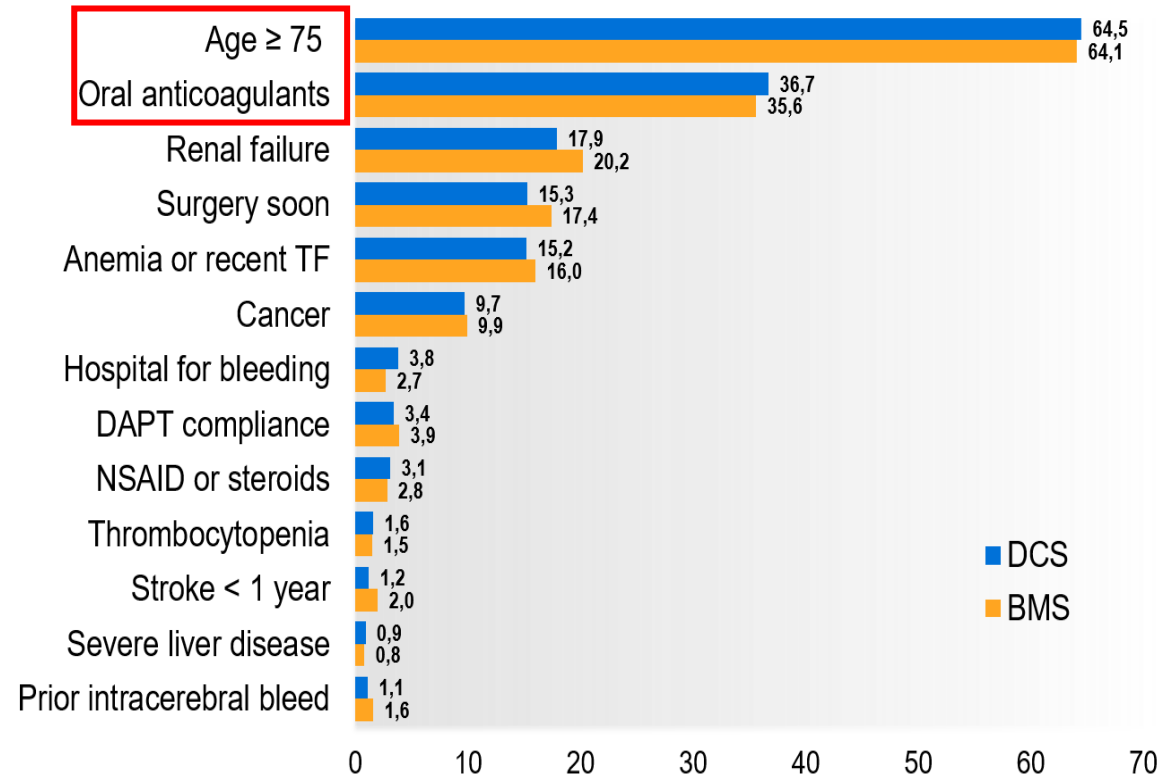


HBR in PCI Trials | Inclusion Criteria

	ZEUS HBR	LEADERS FREE	SENIOR	MASTER DAPT	EVOLVE SHORT DAPT	XIENCE 90 SHORT DAPT	ONYX ONE	COBRA REDUCE
Age ≥ 75 (or 80)								
Renal failure								
Liver disease								
Recent cancer								
Anaemia or TF								
Thrombocytopenia								
Stroke/ICH								
Actionable bleed								
Hospital for bleeding								
OAC								
NSAID								
Surgery soon								
PRECISE DAPT >25								

LEADERS FREE free inclusion criteria

Inclusion Criteria Applied (1.7 Criteria / Patient)



How to improve management of HBR situations ?

How the doctor can optimize his management ?

1. By Stent and revascularisation strategies !

Revascularisation strategies for HBR patient

1. Avoid invasive procedure in HBR patients sometimes !

Case

Woman, 91 y.o, Permanent AF on VKA
Chronic renal dysfunction (CC 25 ml/min)
Hb 8,7 g
Prior History of bleeding 2009

NSTEMI with Tn 27 µg
Good LV function

Very **HBR patients**: age, prior bleedings, CKD, Hb
Decision: **No Invasive procedure**

Revascularisation strategies for HBR patient

1. Avoid invasive procedure in HBR patients sometimes !
2. Avoid PCI in HBR patients sometimes !

Woman, 82 y.o, Permanent AF
LAA Closure for IC bleeding on OAC
Prior History of GI bleeding 2009 on ASA

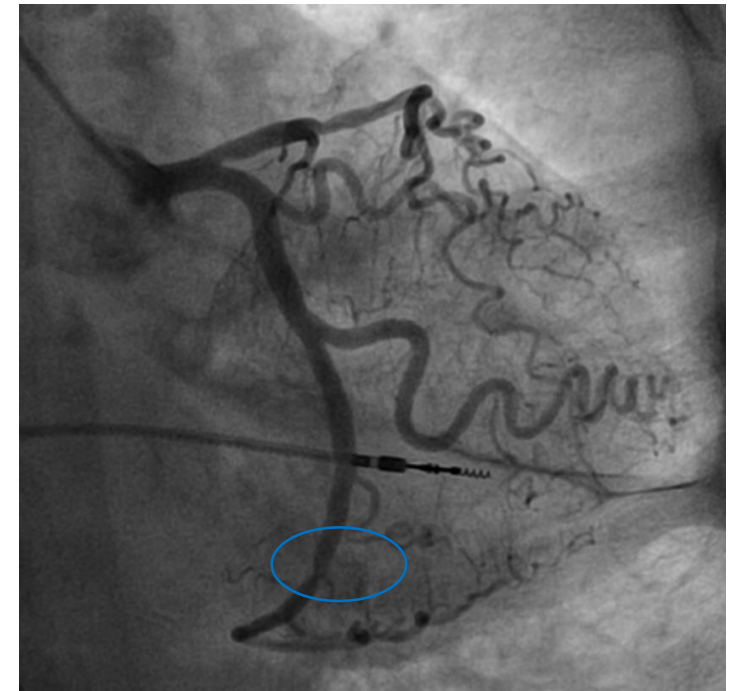
Symptomatic and severe AS ($0.45 \text{ cm}^2/\text{m}^2$, EF 60%)
TAVI candidates with TF access

Significant stenosis distal Cx

Very **HBR patients**: age, prior bleedings

Decision: **No PCI to avoid DAPT** and ASA only post TAVI

Case





















Revascularisation strategies for HBR patient

1. Avoid invasive procedure in HBR patients sometimes !
- 2 Avoid PCI in HBR patients sometimes !
3. Optimize PCI results to be able to stop DAPT earlier

Revascularisation strategies for HBR patient

1. Avoid invasive procedure in HBR patients sometimes !
2. Avoid PCI in HBR patients sometimes !
3. Optimize PCI results to be able to stop DAPT earlier
4. Choose a device effective and safe with short DAPT ?

HBR in PCI Trials | Inclusion Criteria

	ZEUS HBR	LEADERS FREE	SENIOR
Age ≥ 75 (or 80)			
Renal failure			
Liver disease			
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Actionable bleed			
Hospital for bleeding			
OAC			
NSAID			
Surgery soon			
PRECISE DAPT >25			

Is Bare-Metal Stent Implantation Still Justifiable in High Bleeding Risk Patients Undergoing Percutaneous Coronary Intervention?

A Pre-Specified Analysis From the ZEUS Trial

Sara Ariotti, MD,^{a,b} Marianna Adamo, MD,^b Francesco Costa, MD,^b Athanasios Patialiakas, MD,^c Carlo Briguori, MD, PhD,^d Attila Thury, MD, PhD,^e Salvatore Colangelo, MD,^f Gianluca Campo, MD,^g Matteo Tebaldi, MD,^h Imre Ungi, MD, PhD,^o Stefano Tondi, MD,^h Marco Roffi, MD,¹ Alberto Menozzi, MD, PhD,¹ Nicoletta de Cesare, MD,² Roberto Garbo, MD,¹ Emanuele Meliga, MD,¹ Luca Testa, MD, PhD,^{2,3} Henrique Mesquita Gabriel, MD,⁴ Marco Ferlini, MD,⁵ Pascal Vranckx, MD, PhD,⁶ Marco Valgimigli, MD, PhD,^{a,b} for the ZEUS Investigators

Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk

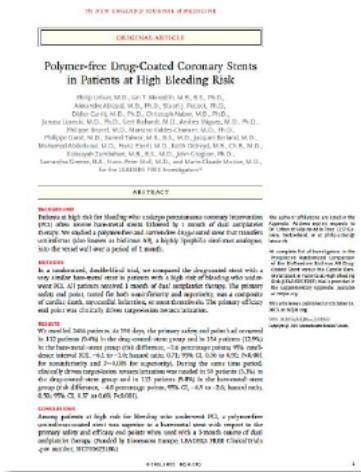
Philip Urban, M.D., Ian T. Meredith, M.B., B.S., Ph.D., Alexandre Abizaid, M.D., Ph.D., Stuart J. Pocock, Ph.D., Didier Carrié, M.D., Ph.D., Christoph Naber, M.D., Ph.D., Janusz Lipiecki, M.D., Ph.D., Gert Richardt, M.D., Andres Iñiguez, M.D., Ph.D., Philippe Brunel, M.D., Mariano Valdes-Chavarrí, M.D., Ph.D., Philippe Garot, M.D., Suneel Talwar, M.B., B.S., M.D., Jacques Berland, M.D., Mohamed Abdellaoui, M.D., Franz Eberli, M.D., Keith Oldroyd, M.B., Ch.B., M.D., Robaayah Zambahari, M.B., B.S., M.D., John Gregson, Ph.D., Samantha Greene, B.A., Hans-Peter Stoll, M.D., and Marie-Claude Morice, M.D., for the LEADERS FREE Investigators*

Drug-eluting stents in elderly patients with coronary artery disease (SENIOR): a randomised single-blind trial

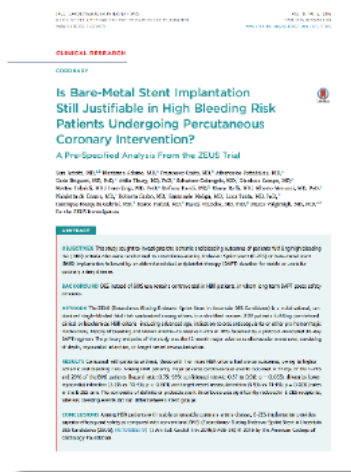
Olivier Varenne, Stéphane Cook, Georgios Sideris, Sasko Kedev, Thomas Crisset, Didier Carrié, Thomas Howasse, Philippe Garot, Rami El Mahmoud, Christian Spaulding, Gérard Helft, José F Díaz Fernández, Salvatore Brugaletta, Eduardo Pinar-Bermudez, Josepa Mauri Ferré, Philippe Cormeau, Emmanuel Teiger, Kris Bogaerts, Manel Sabate, Marie-Claude Morice, Peter R Sinnaeve, for the SENIOR investigators

3 completed & published trials of short DAPT (≤ 3 months) for HBR patients

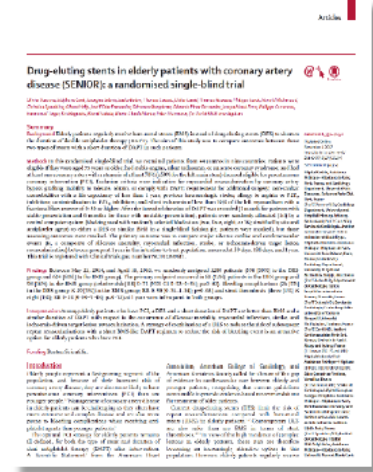
LEADERS FREE



ZEUS HBR



SENIOR



« Device studies »

If HBR + mandatory short DAPT: DCS/DES better than BMS

NOT « DAPT studies »

Showing that we can use short DAPT for all patients with these devices
Ongoing (MASTER DAPT and others)

Options for Device in HBR patients

BMS ... ?

No longer an option after LEADERS FREE / SENIOR / ZEUS !

New generation DES

Drug-coated stent

How to improve management of HBR situations ?

How the doctor can optimize his management ?

1. By Stent and revascularisation strategies !
2. By Antithrombotic strategy to reduce bleeding

Antithrombotic strategy for HBR patient

DAPT regimen

Low dose of aspirin (≤ 100 mg)

PPI in High-risk Patient

Consider **Less potent P2Y12** inhibition even in ACS (Clopidogrel)

Shorter DAPT duration if possible (1-3-6 in ACS / 1-3 in elective PCI)

If not, Consider early **switch** in ACS patients (Prasu/Tica \longrightarrow Clopi)

Very Short DAPT if OAC or double therapy without ASA

How to improve management of HBR situations ?

How the doctor can optimize his management ?

1. By Stent and revascularisation strategies !
2. By Antithrombotic strategy to reduce bleeding
3. Difference between ACS and SCAD ?

SCAD vs ACS in HBR patients

PCI + **SCAD** : new device allow very short DAPT

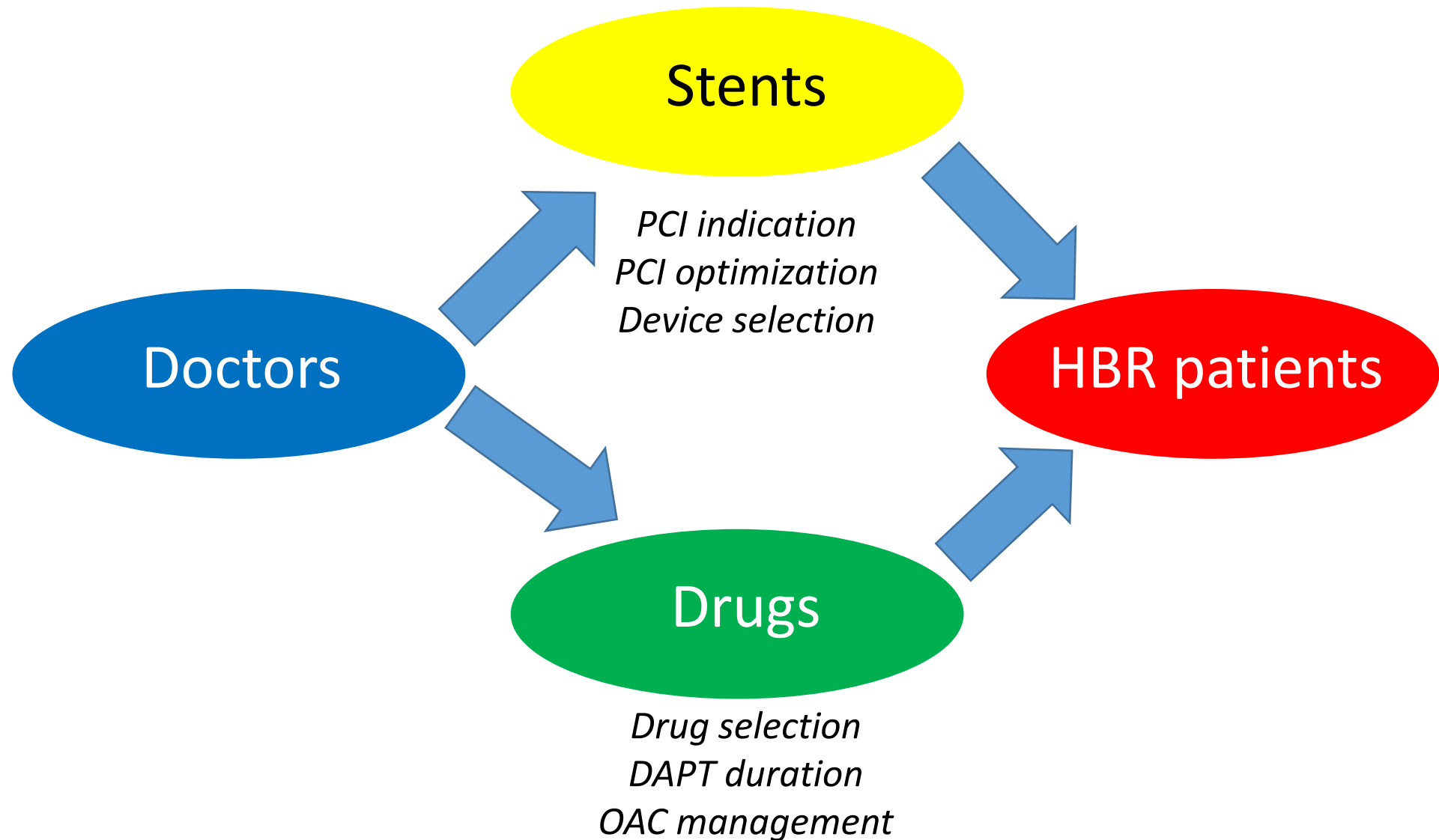
PCI + **ACS**: ACS is an argument for longer DAPT

PCI + **HBR**: HBR is an argument for shorter DAPT

PCI + **SCAD + HBR** : new device allow very short DAPT

PCI + **ACS + HBR** : Individual decision for each patient

Optimal Management of HBR patient



Qui est à haut risque hémorragique ?

Conclusion

Identification of HBR patients

Scores vs clinical judgment / Age and OAC as main factors in daily practice

Doctor has a KEY role for bleeding prevention in HBR patients

Need for information, education and studies in this specific field

PCI strategies specific to HBR patients

Dedicated strategies, device selection

Antithrombotic strategies to be tailored in HBR patients

Less potent drugs and shorter duration / Challenge in ACS (Speakers)

• Washington, USA
Friday, April 13-14, 2018



ARC-HBR group with **ARC definition of HBR** coming soon ...