

# **DAPT po implantaci DES kratší 3 měsíce : ANO !**

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28.workshop ČAIK

Hradec Králové 11.-13.4.2018



# DAPT podle ACC / AHA 2016

## Focused Update on Duration of Dual Antiplatelet Therapy

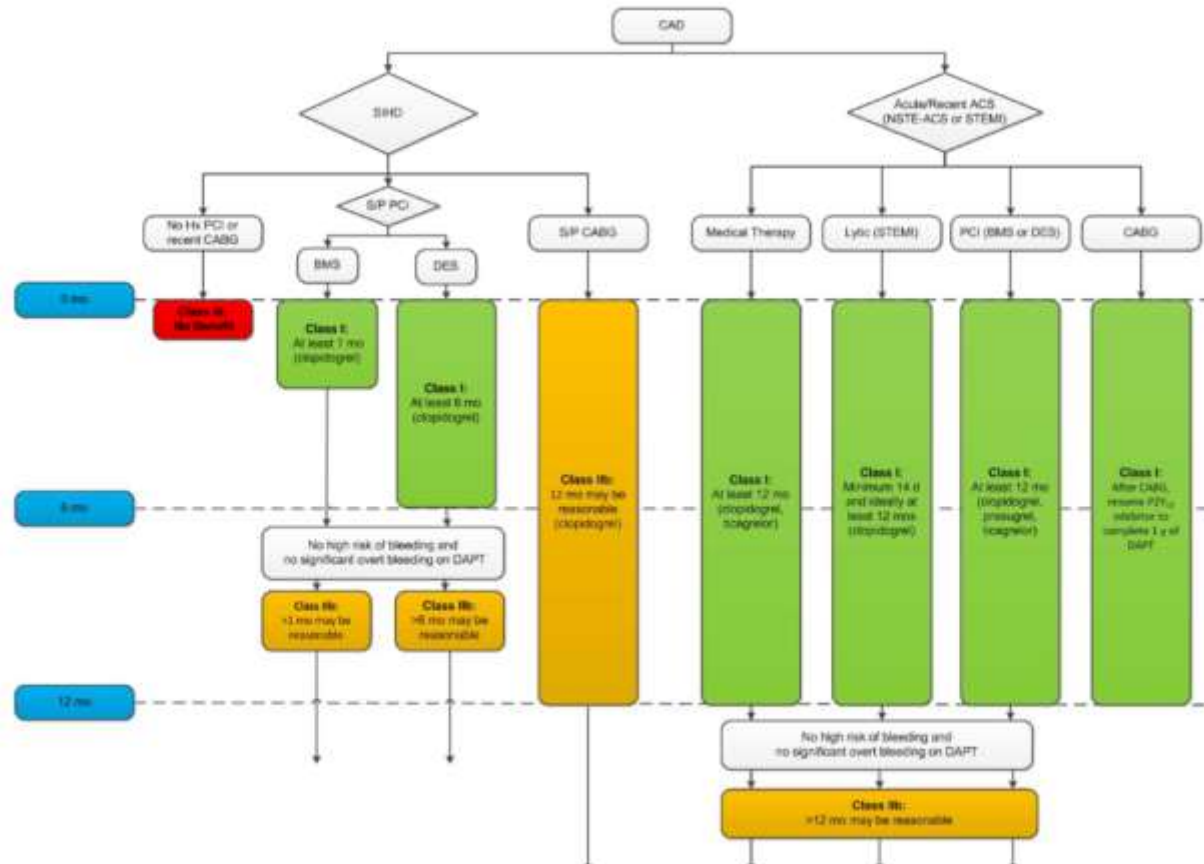
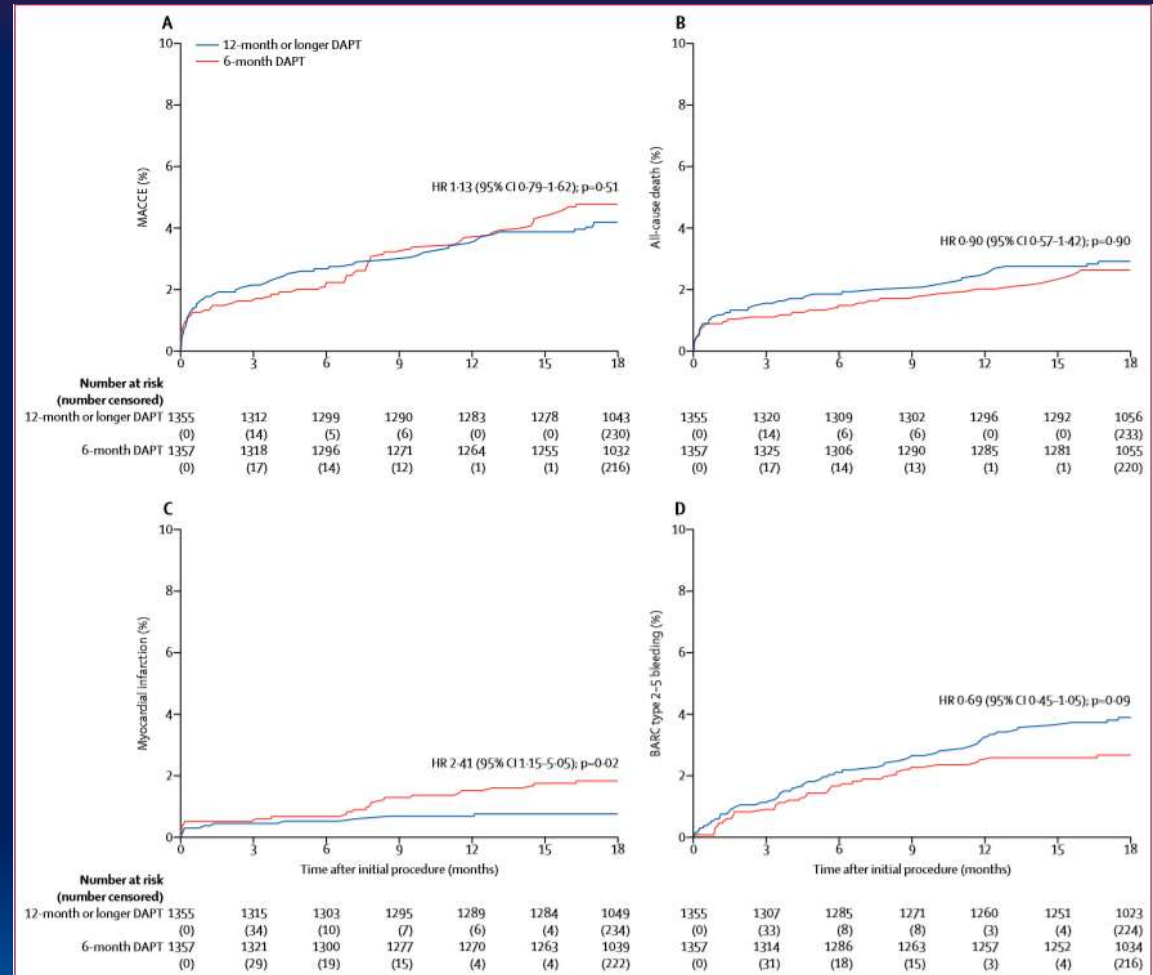
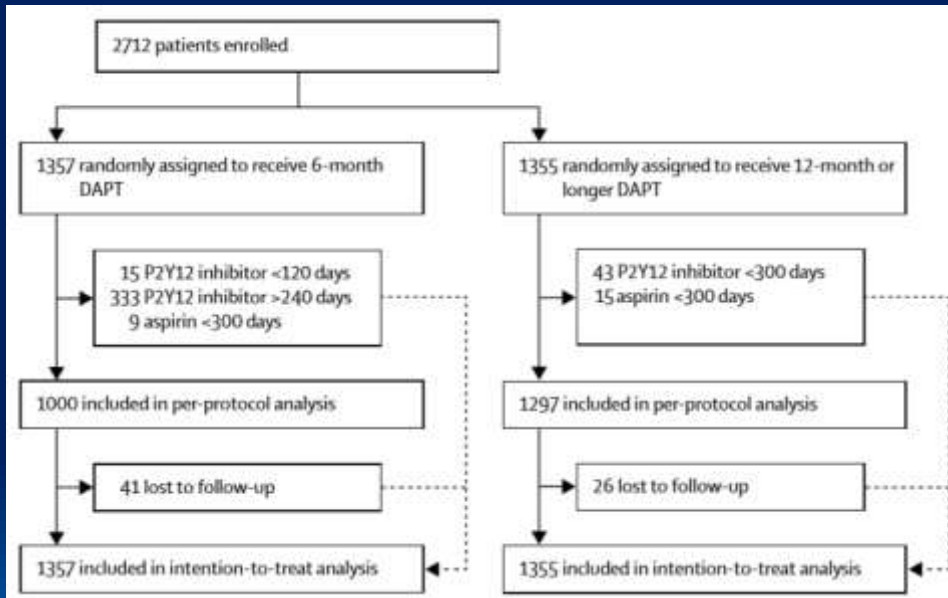


Figure 1. Master Treatment Algorithm for Duration of P2Y<sub>12</sub> Inhibitor Therapy in Patients With CAD Treated With DAPT

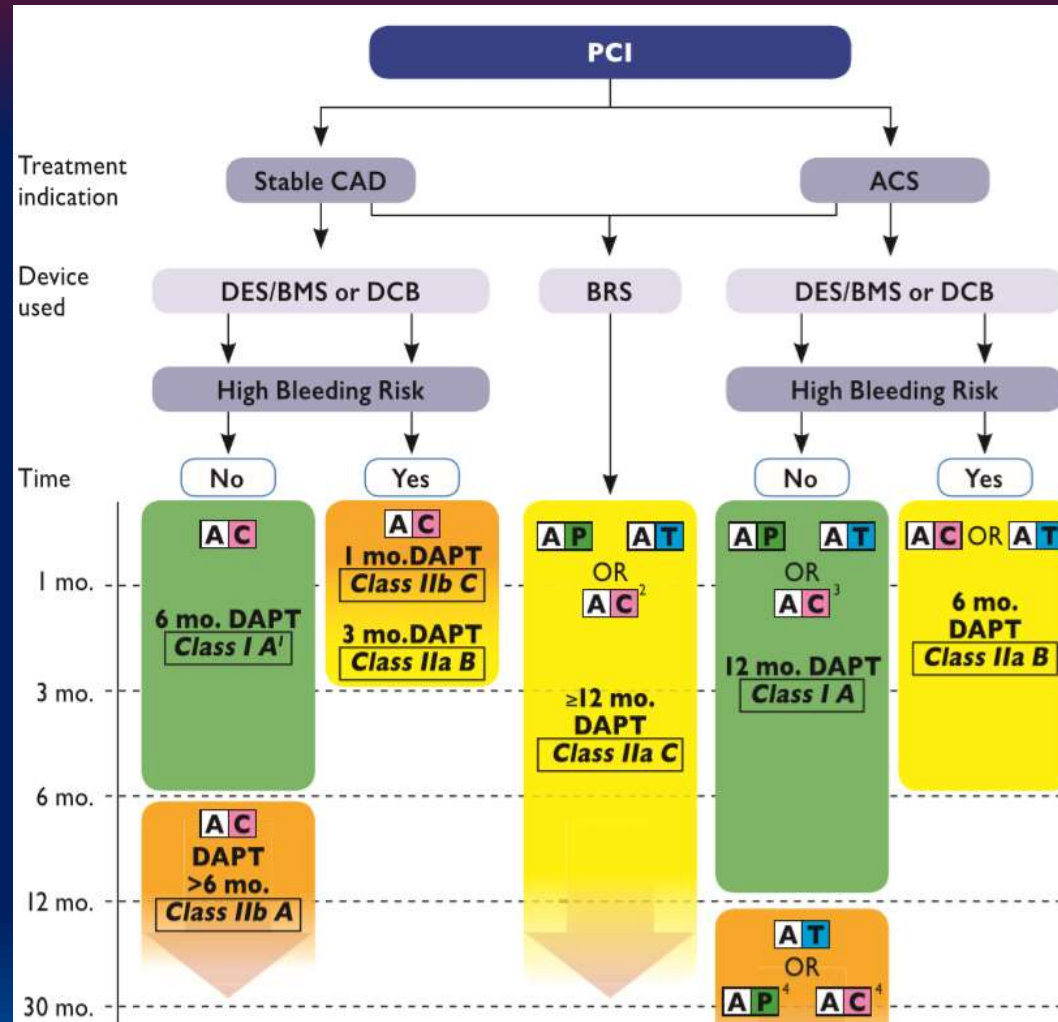
# DAPT po PCI při ACS : pokud je to možné, 12 měsíců

## 6-month versus 12-month or longer dual antiplatelet therapy after percutaneous coronary intervention in patients with acute coronary syndrome (SMART-DATE): a randomised, open-label, non-inferiority trial

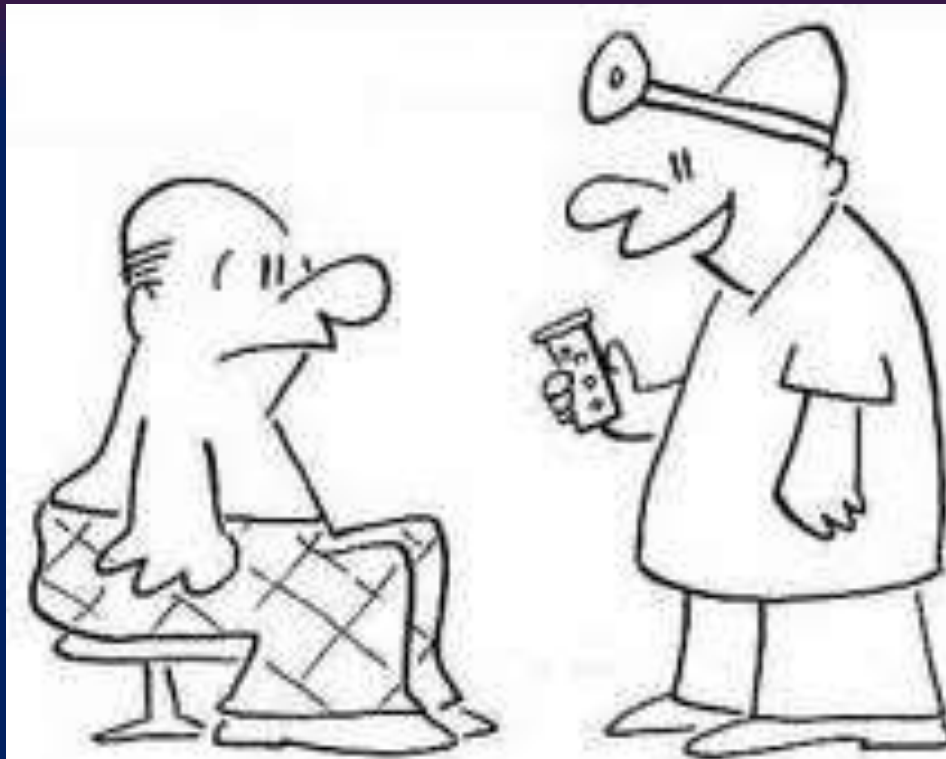
Joo-Yong Hahn\*, Young Bin Song\*, Ju-Hyeon Oh, Deok-Kyu Cho, Jin Bae Lee, Joon-Hyung Doh, Sang-Hyun Kim, Jin-Ok Jeong, Jang-Ho Bae, Byung-Ok Kim, Jang Hyun Cho, Il-Woo Suh, Doo-il Kim, Hoon-Ki Park, Jong-Seon Park, Woong Gil Choi, Wang Soo Lee, Jihoon Kim, Ki Hong Choi, Taek Kyu Park, Joo Myung Lee, Jeong Hoon Yang, Jin-Ho Choi, Seung-Hyuk Choi, Hyeon-Cheol Gwon, for the SMART-DATE investigators†



# DAPT podle ESC 2017

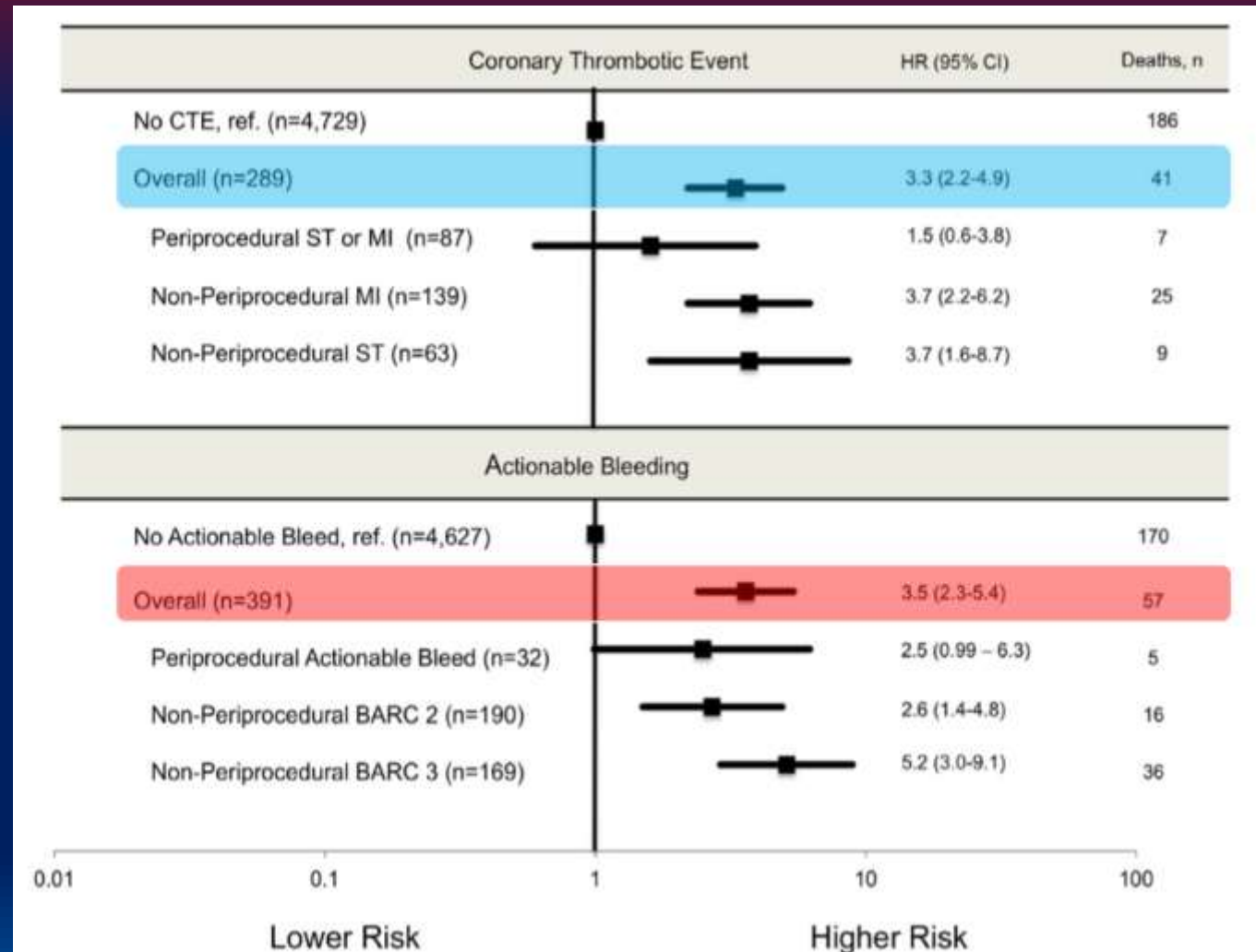


## Proč zavádíme kategorii HBR (high-bleeding risk) ?

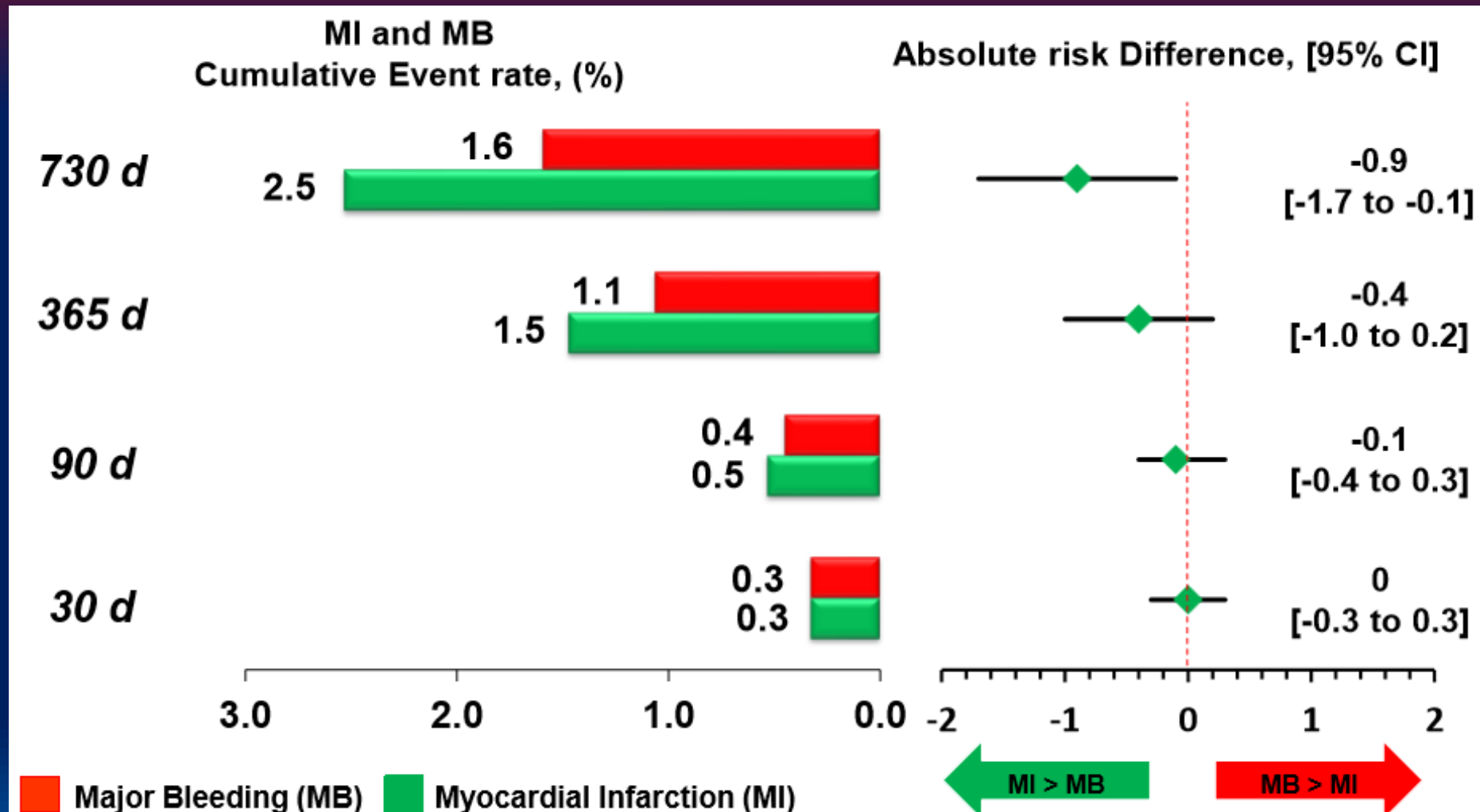


"The FDA hasn't approved these pills yet, but the CIA swears by them!"

# DAPT : vliv na mortalitu má **POSTPROCEDURÁLNÍ** krvácení !

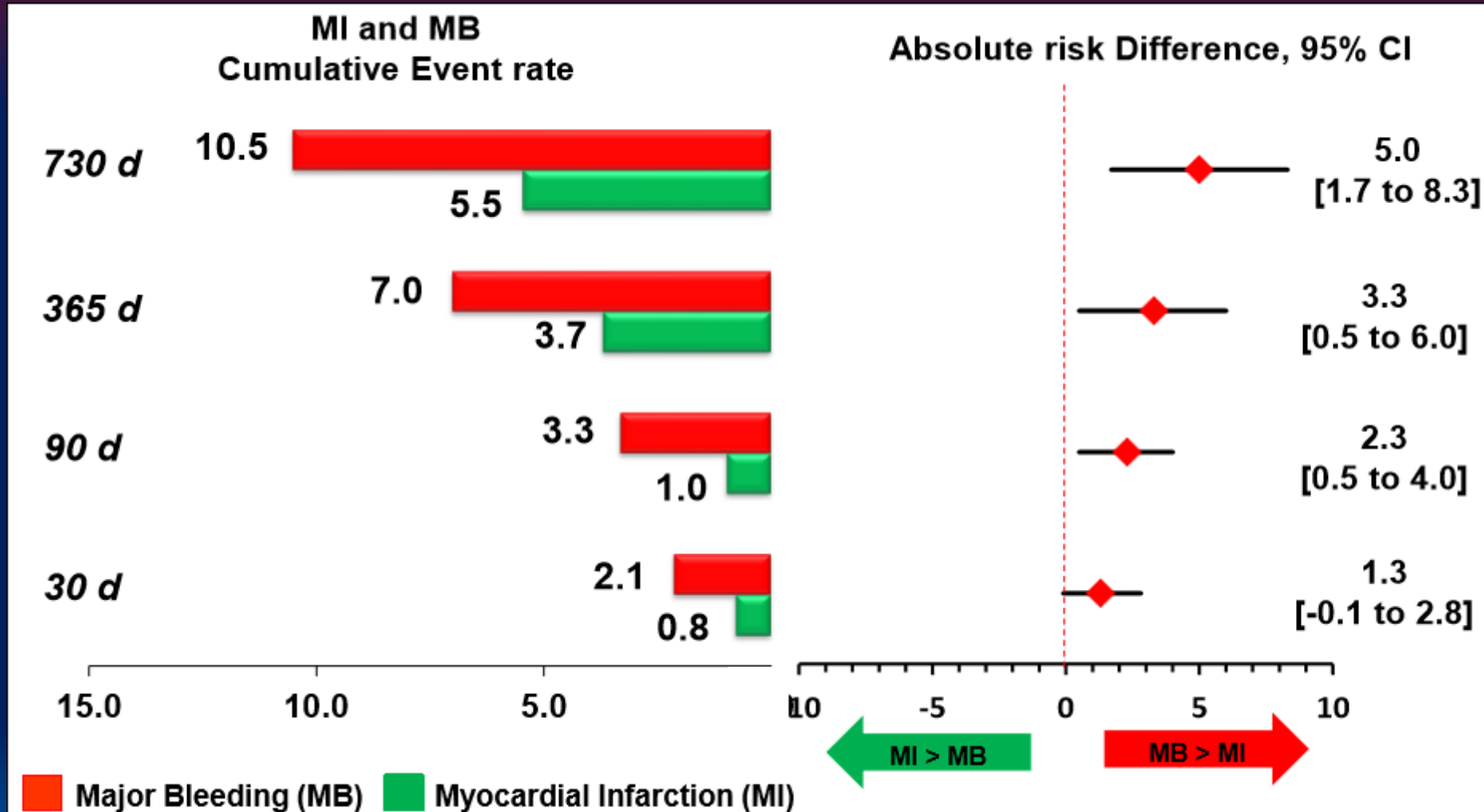


# Riziko krváčení při DAPT : low bleeding risk



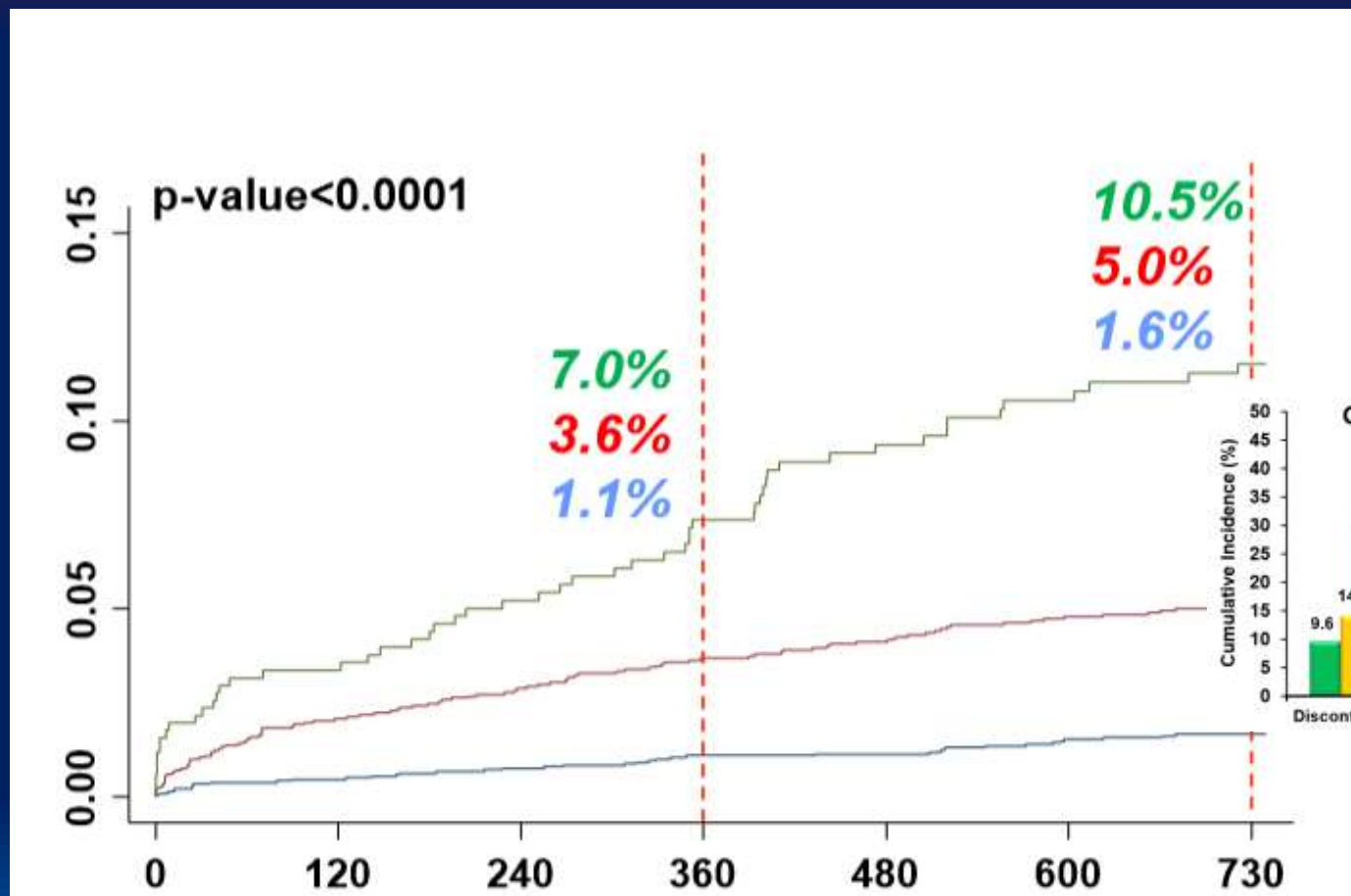


# Riziko krváčení při DAPT : high bleeding risk (HBR)

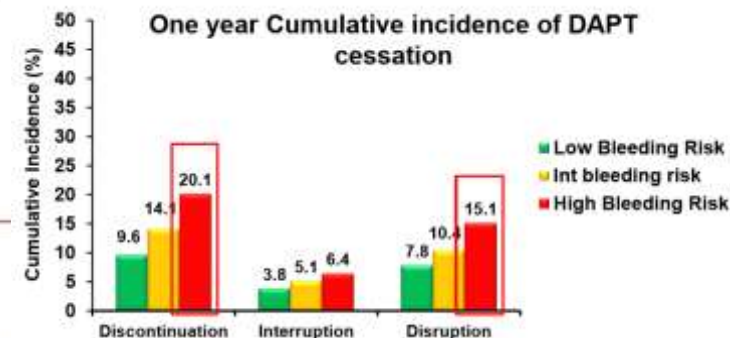


# Závažná krvácení : vývoj v čase

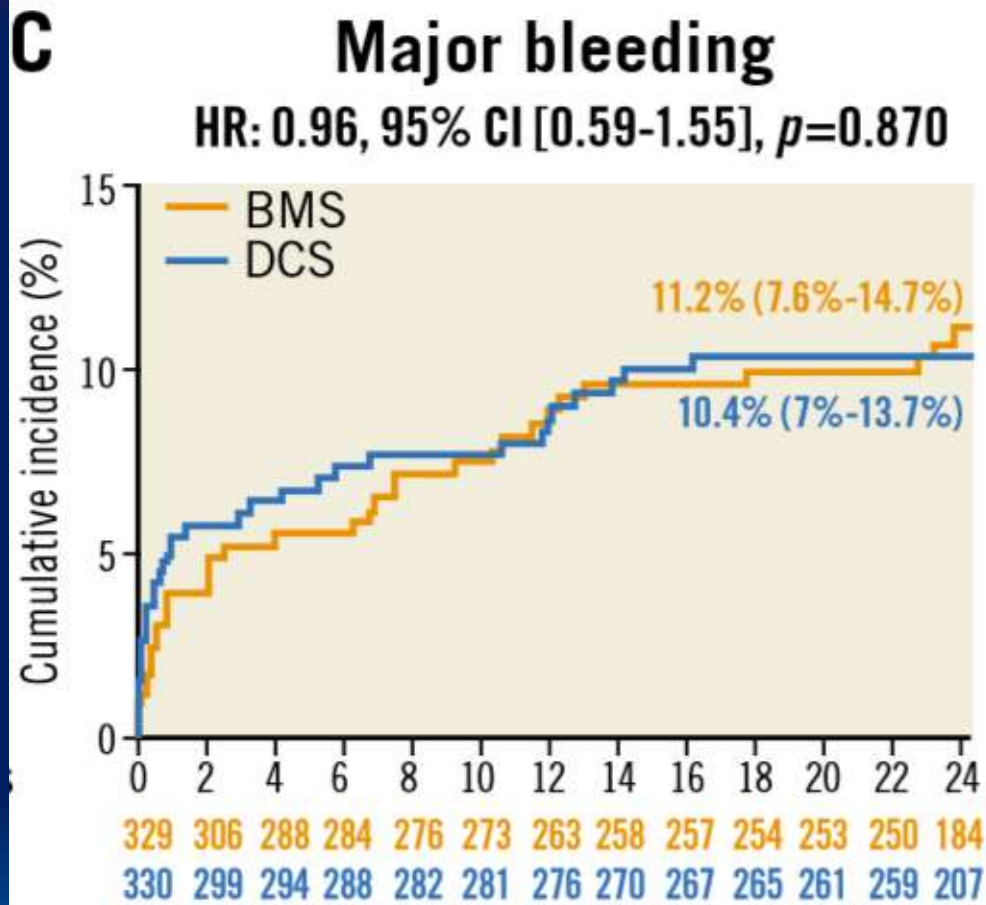
— Low Bleeding Risk — Int. Bleeding Risk — High Bleeding Risk



One year Cumulative incidence of DAPT cessation



# Riziko krváčení při DAPT : **HBR patients**

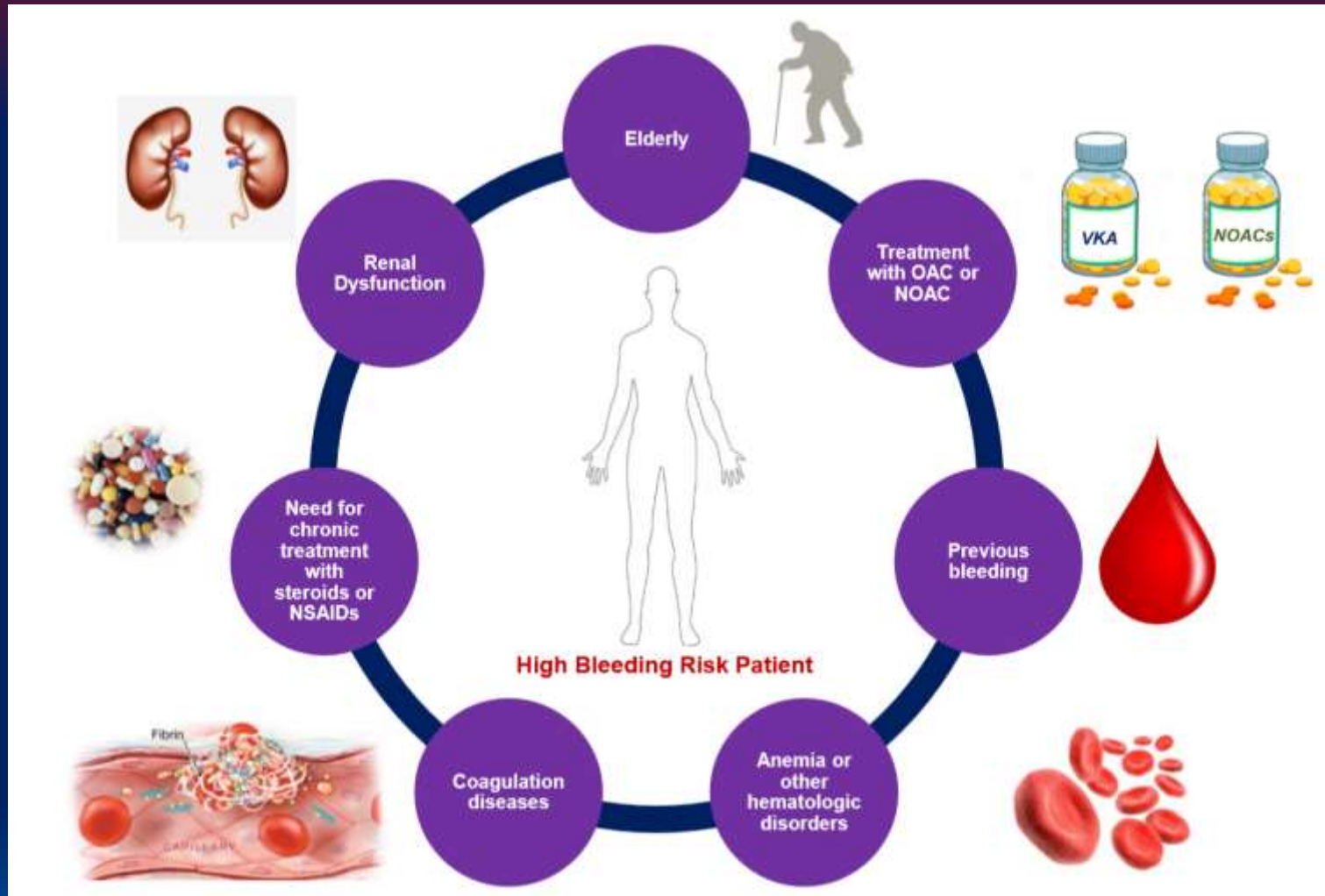


EuroIntervention 2018;13:1946-1949

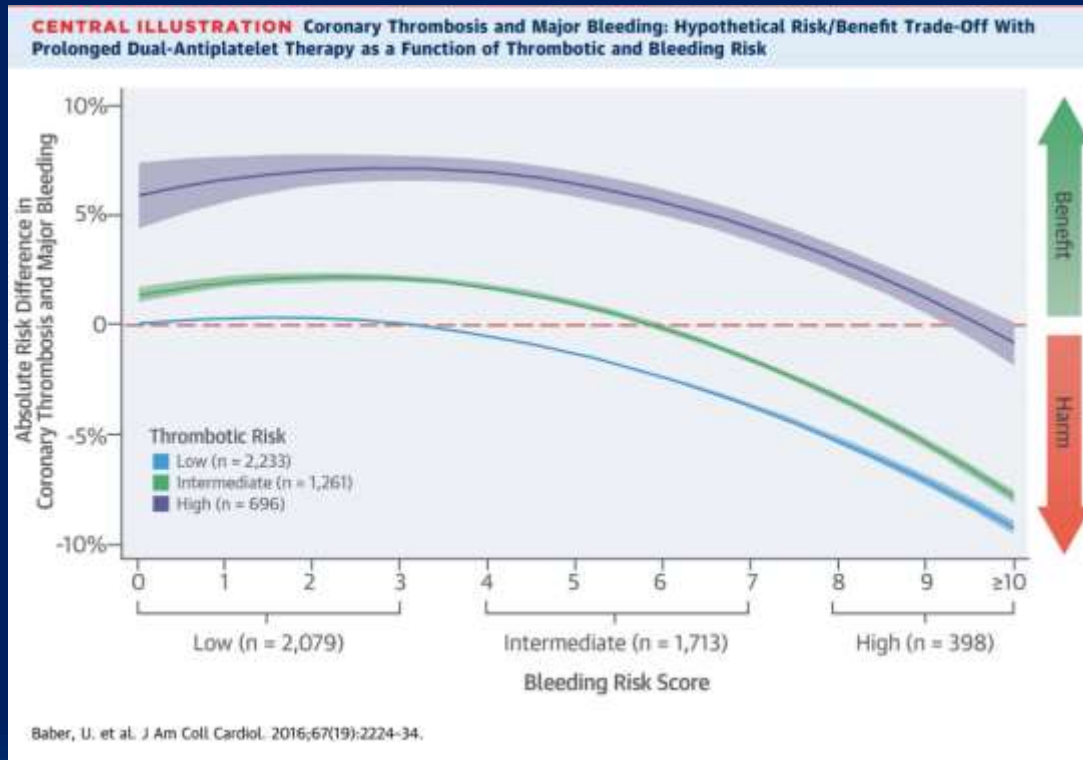
- Type 3a
  - Overt bleeding plus hemoglobin drop of 3 to <5 g/dL\* (provided hemoglobin drop is related to bleed)
  - Any transfusion with overt bleeding
- Type 3b
  - Overt bleeding plus hemoglobin drop  $\geq 5$  g/dL\* (provided hemoglobin drop is related to bleed)
  - Cardiac tamponade
  - Bleeding requiring surgical intervention for control (excluding dental/nasal/skin/hemorrhoid)
  - Bleeding requiring intravenous vasoactive agents
- Type 3c
  - Intracranial hemorrhage (does not include microbleeds or hemorrhagic transformation, does include intraspinal)
  - Subcategories confirmed by autopsy or imaging or lumbar puncture
  - Intraocular bleed compromising vision
- Type 4: CABG-related bleeding
  - Perioperative intracranial bleeding within 48 h
  - Reoperation after closure of sternotomy for the purpose of controlling bleeding
  - Transfusion of  $\geq 5$  U whole blood or packed red blood cells within a 48-h period†
  - Chest tube output  $\geq 2$ L within a 24-h period
- Type 5: fatal bleeding

Circulation. 2011;123:2736-2747.

# Kdo je „HBR“ pacient ?



# Riziko krváčení při DAPT : PARIS score



Parameter	Score				
Age, years	< 50	50-59	60-69	70-79	>80
	0	+1	+2	+3	+4
BMI, kg/m <sup>2</sup>	<25		25-34.9	> 35	
	+2		0	+2	
Current Smoking	Yes +2		No 0		
Anemia	Present +3		Absent 0		
CrCl <60 ml/min	Present +2		Absent 0		
TT* on discharge	Yes +2		No 0		

# Riziko krváčení při DAPT : PRECISE-DAPT

	PRECISE-DAPT score <sup>16</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>†</sup>	<p>HB <math>\geq 12</math> 11.5 11 10.5 <math>\leq 10</math></p> <p>WBC <math>\leq 5</math> 8 10 12 14 16 18 <math>\geq 20</math></p> <p>Age <math>\leq 50</math> 60 70 80 <math>\geq 90</math></p> <p>CrCl <math>\geq 100</math> 80 60 40 20 0</p> <p>Prior Bleeding No Yes</p> <p>Score Points 0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30</p>	<p>Age <math>\geq 75</math> -2 pt 65 to &lt;75 -1 pt &lt;65 0 pt</p> <p>Cigarette smoking +1 pt Diabetes mellitus +1 pt MI at presentation +1 pt Prior PCI or prior MI +1 pt Paclitaxel-eluting stent +1 pt Stent diameter &lt;3 mm +1 pt CHF or LVEF &lt;30% +2 pt Vein graft stent +2 pt</p>
Score range	0 to 100 points	-2 to 10 points
Decision making cut-off suggested	Score $\geq 25$ → Short DAPT Score <25 → Standard/long DAPT	Score $\geq 2$ → Long DAPT Score <2 → Standard DAPT
Calculator	<a href="http://www.precisedaptscore.com">www.precisedaptscore.com</a>	<a href="http://www.daptstudy.org">www.daptstudy.org</a>

**PRECISEDAPT** Home WebCalculator Disclaimer About Contact Us

Hemoglobin: 11 unit g/dL mmol/L

Age (years): 60

White blood cells: 20 unit  $\times 10^9/L$

Creatinine Clearance (mL/min): 35

Prior Bleeding: No

**CALCULATE** **RESET**

**RESULT**

Cluster of risk: **High**

Score Calculated: **64**

12 months risk of TIMI major or minor Bleeding: **> 4.14%**

12 months risk of TIMI Major Bleeding: **> 2.06%**

**Copy to clipboard**

**HBR pacient** : DAPT po implantaci DES kratší 3 měsíce!

Kategorie	Název kategorie
78001	Kategorie BMS (Bare metal Stents)
78002	DES s trvalým polymerem
78003	DES s biodegradabilním polymerem
78004	DES bez polymeru
78005	Biodegradabilní stent
78006	Stent pro speciální indikace (stentgraft, bifurkační stent, samoexpandibilní stent)
78007	DES s možným zkrácením trvání protidestičkové léčby na 1 měsíc

- **BioFreedom** (Biosensors, CH)
- **Synergy** (BSCI, USA)
- **Ultimaster** (Terumo, JPN)

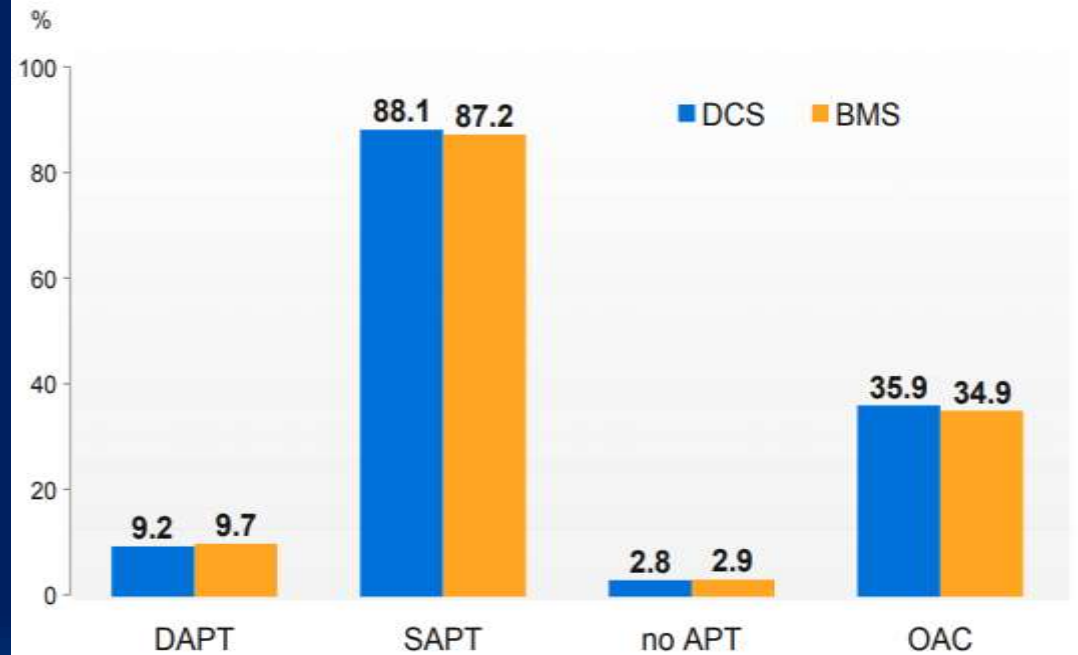
# HBR patient : BioFreedom

## 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 / mm<sup>3</sup>)
- 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

## Antithrombotic Medication after 1 month visit\*

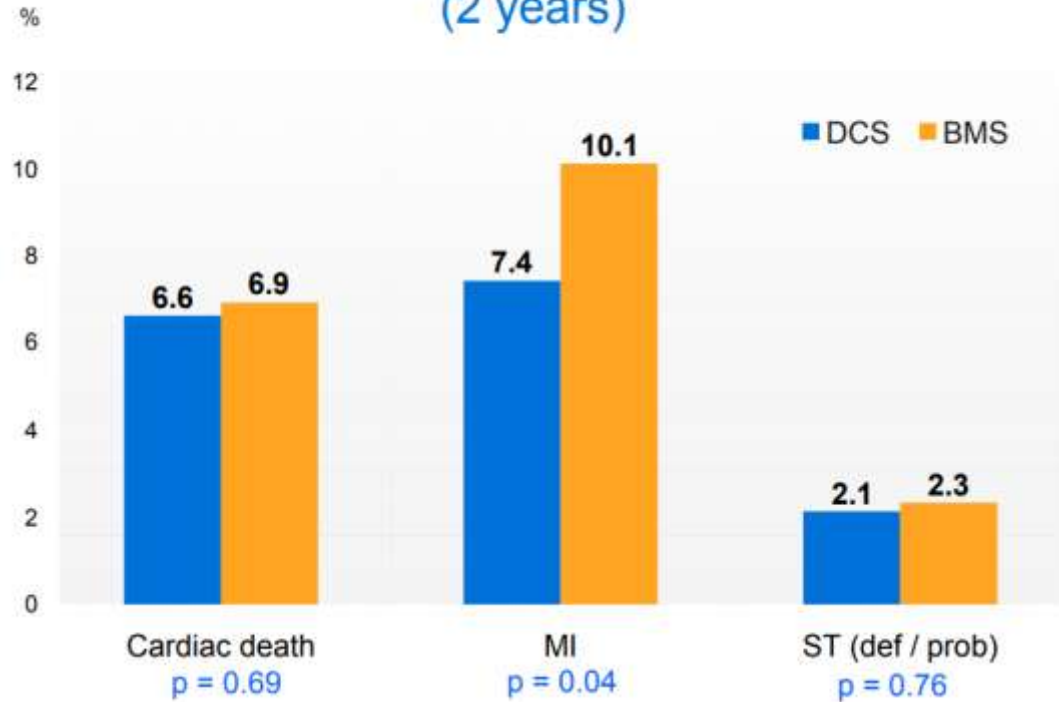
\* at day 37



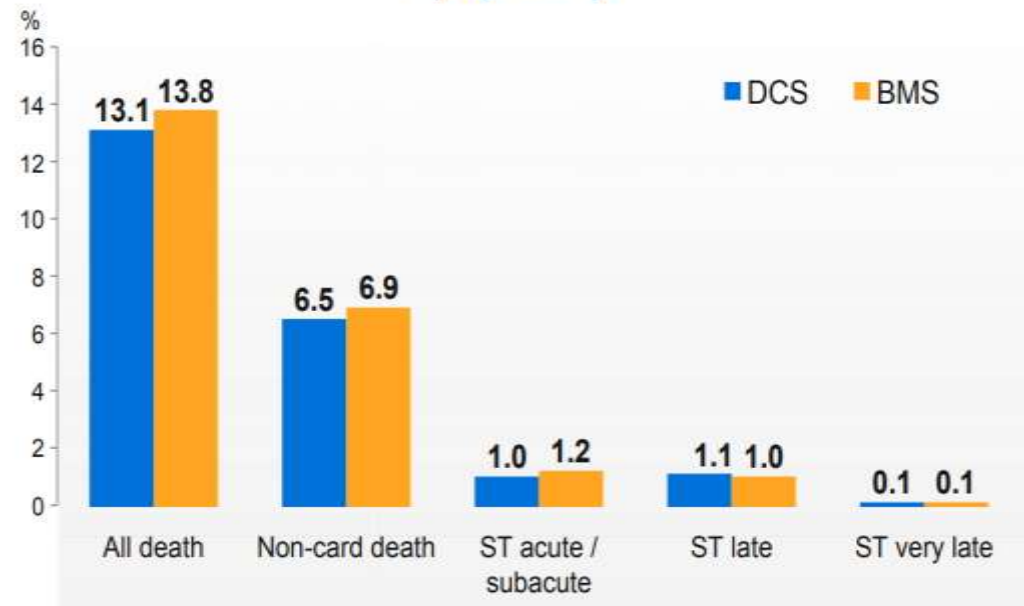


# HBR patient : BioFreedom

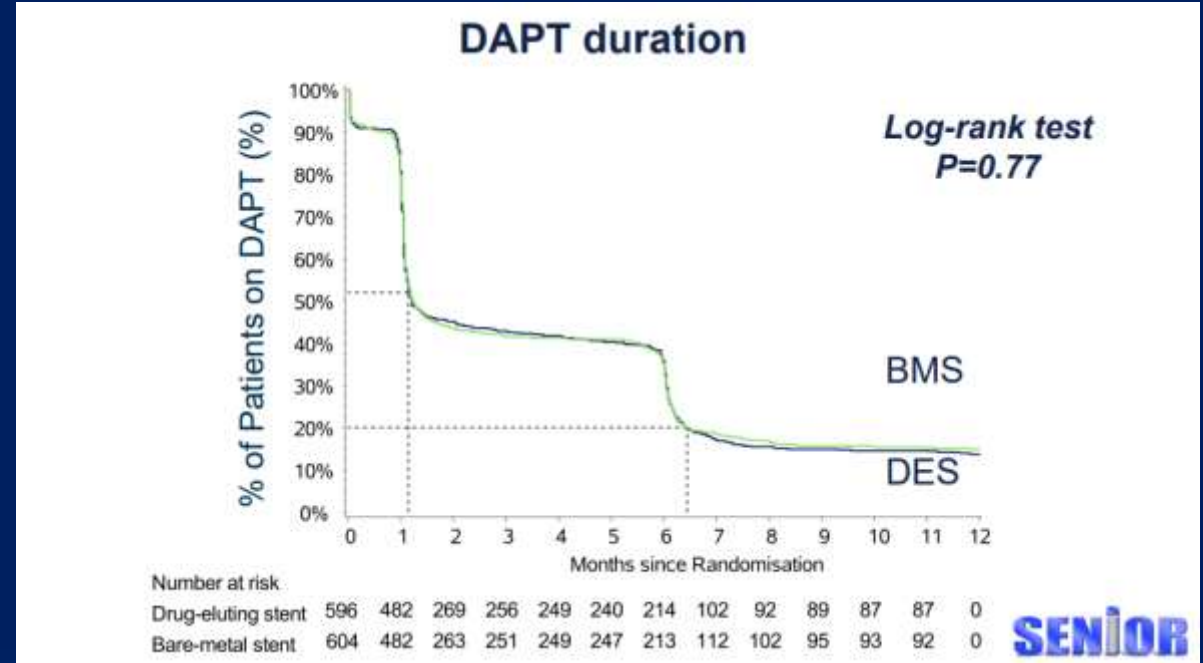
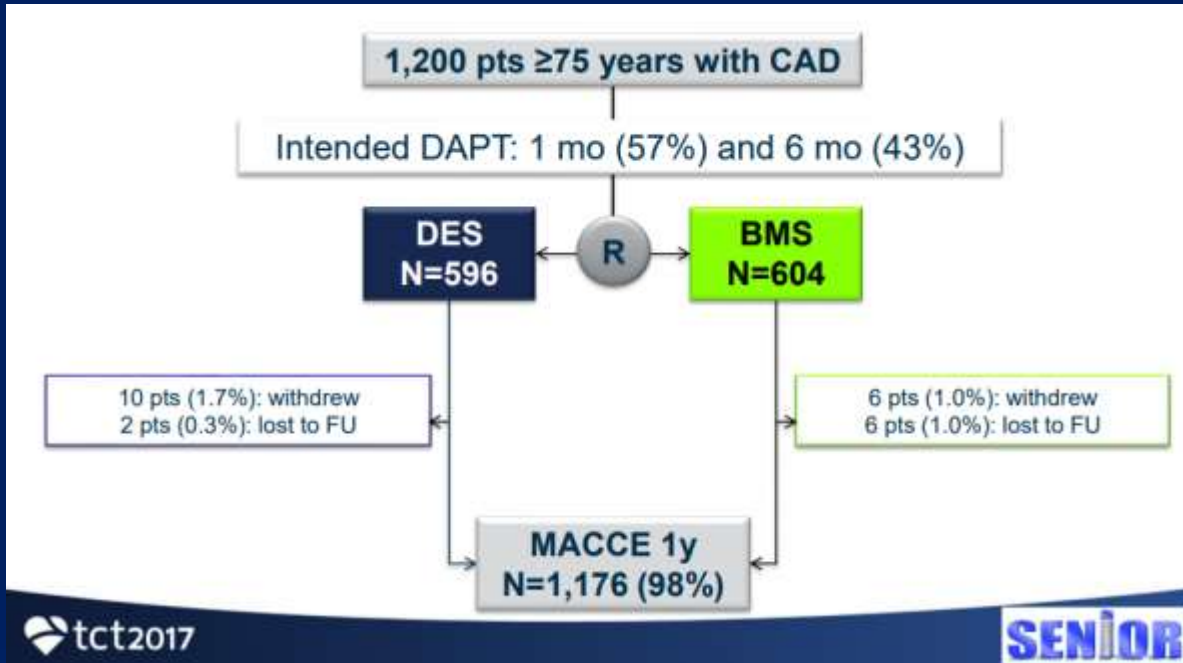
## Components of Safety Endpoint (2 years)



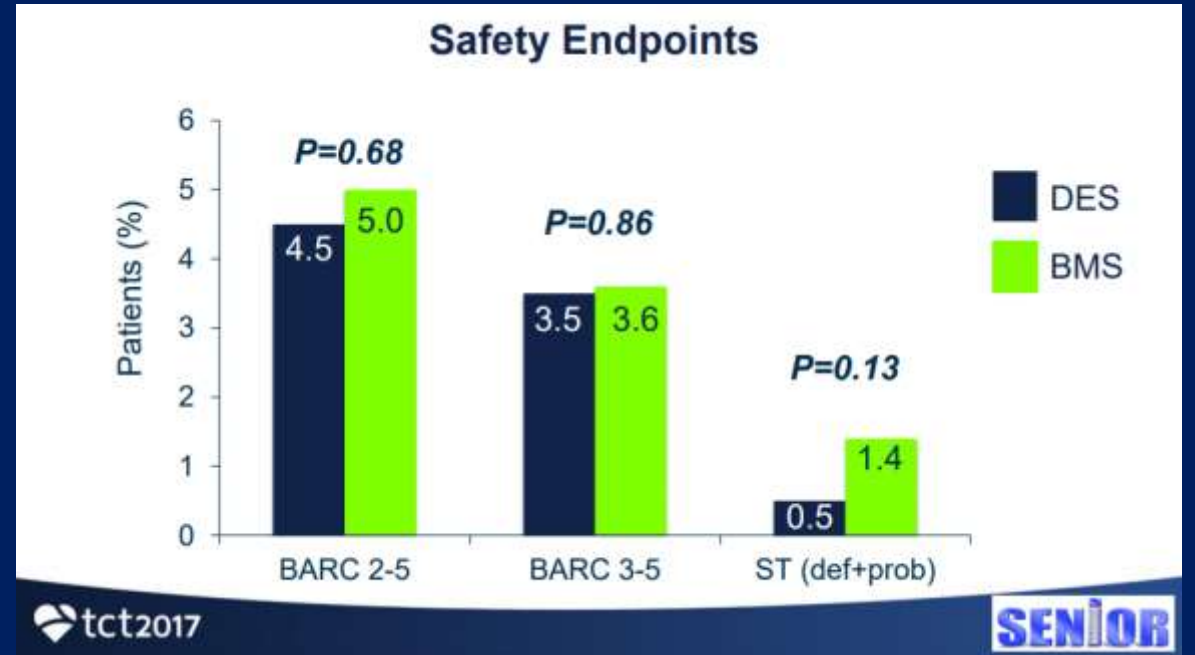
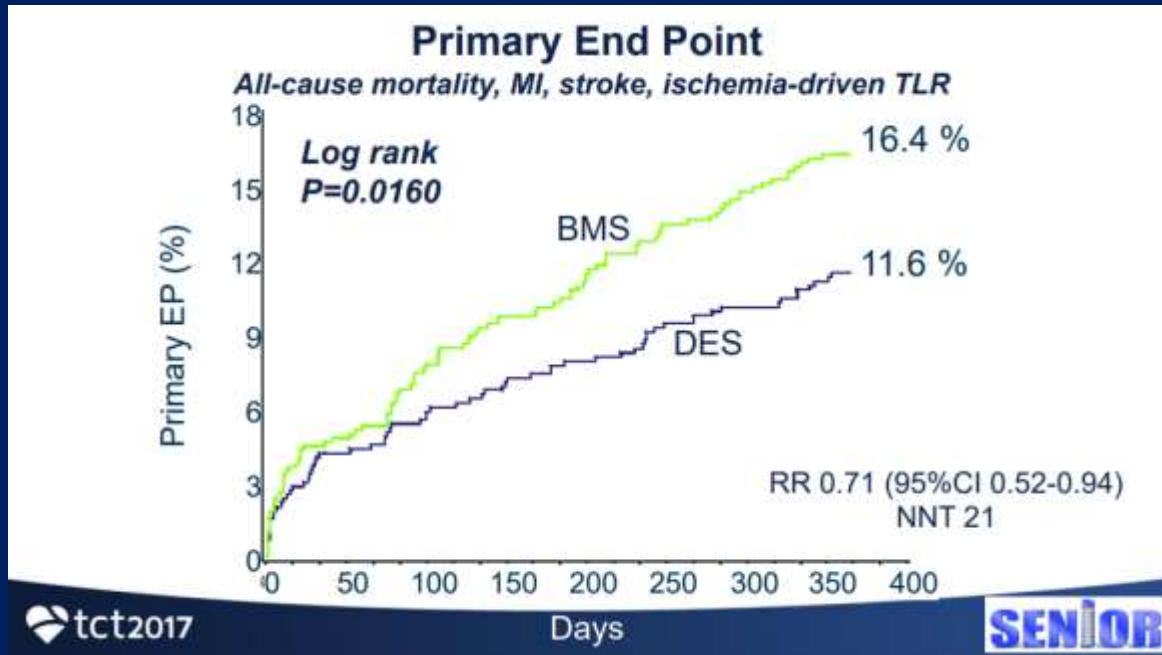
## Selected Secondary Safety Endpoints (2 years)



# HBR patient : Synergy



# HBR patient : Synergy



# HBR patient : Ultimaster

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Trial record **1 of 1** for: master dapt

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**Management of High Bleeding Risk Patients Post Bioresorbable Polymer Coated Stent Implantation With an Abbreviated Versus Prolonged DAPT Regimen (MASTER DAPT)**

## Study Design

Study Type ⓘ	: Interventional (Clinical Trial)
Estimated Enrollment ⓘ	: 4300 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Management of High Bleeding Risk Patients
Actual Study Start Date ⓘ	: April 4, 2017
Estimated Primary Completion Date ⓘ	: October 2019
Estimated Study Completion Date ⓘ	: October 2019

Kontrola ve 3. měsíci po implantaci DES:

DAPT 1 měsíc



DAPT 3 měsíce



DAPT po implantaci DES kratší než 3 měsíce : **ANO !**