1. Plättchenhemmung nach Stent - MASTER-DAPT, STOPDAPT-2 ACS

2. EMPEROR-Preserved / EMPEROR-Pooled

3. Gerinnungshemmung TAVI und Vorhofflimmern – ENVISAGE-TAVI AF

4. Herzinsuffizienz Leitlinien 2021 – Was ist neu ?

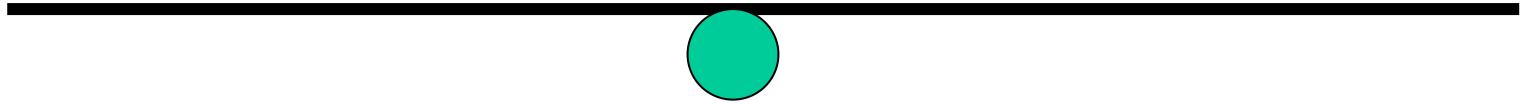
5. Schrittmacher/CRT-Leitlinien 2021 – Was ist neu ?

Plättchenhemmung nach Stent - MASTER-DAPT, STOPDAPT-2 ACS

Prof. Frank R. Heinzel

Kardiologie - Charité
Campus Virchow-Klinikum

Strategien der Gerinnungshemmung nach PCI



Ziel: Verringerung der Blutungskomplikationen
in der (post-)akuten Phase

De-Eskalation

- Reduktion der Intensität der Gerinnungshemmung
- Verkürzung der Dauer der Gerinnungshemmung

Minimierung Triple Therapie
Verkürzung der akuten Phase (< 12 Monate)

Ziel: Verbesserung der Sekundärprophylaxe
in der chronischen Phase

Verlängerung der akuten Phase (> 12 Mo)

- Intensivierung der Gerinnungshemmung
- Verlängerung der Gerinnungshemmung

Prolongiert DAPT
Dual Pathway

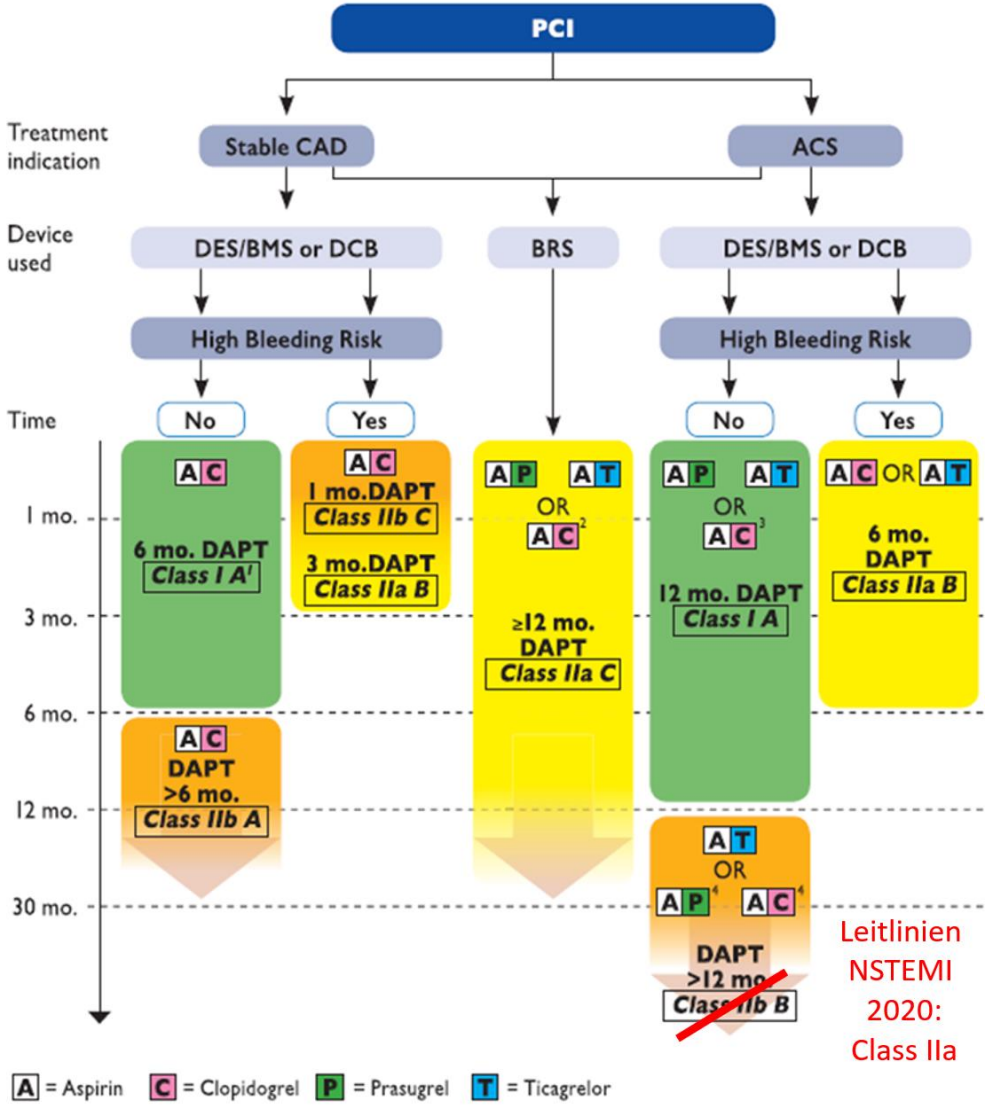
Thrombozytenaggregationshemmung nach PCI

… je nach Blutungsrisiko (und Stent-Typ)

6 Monate DAPT (Klasse I Empfehlung)

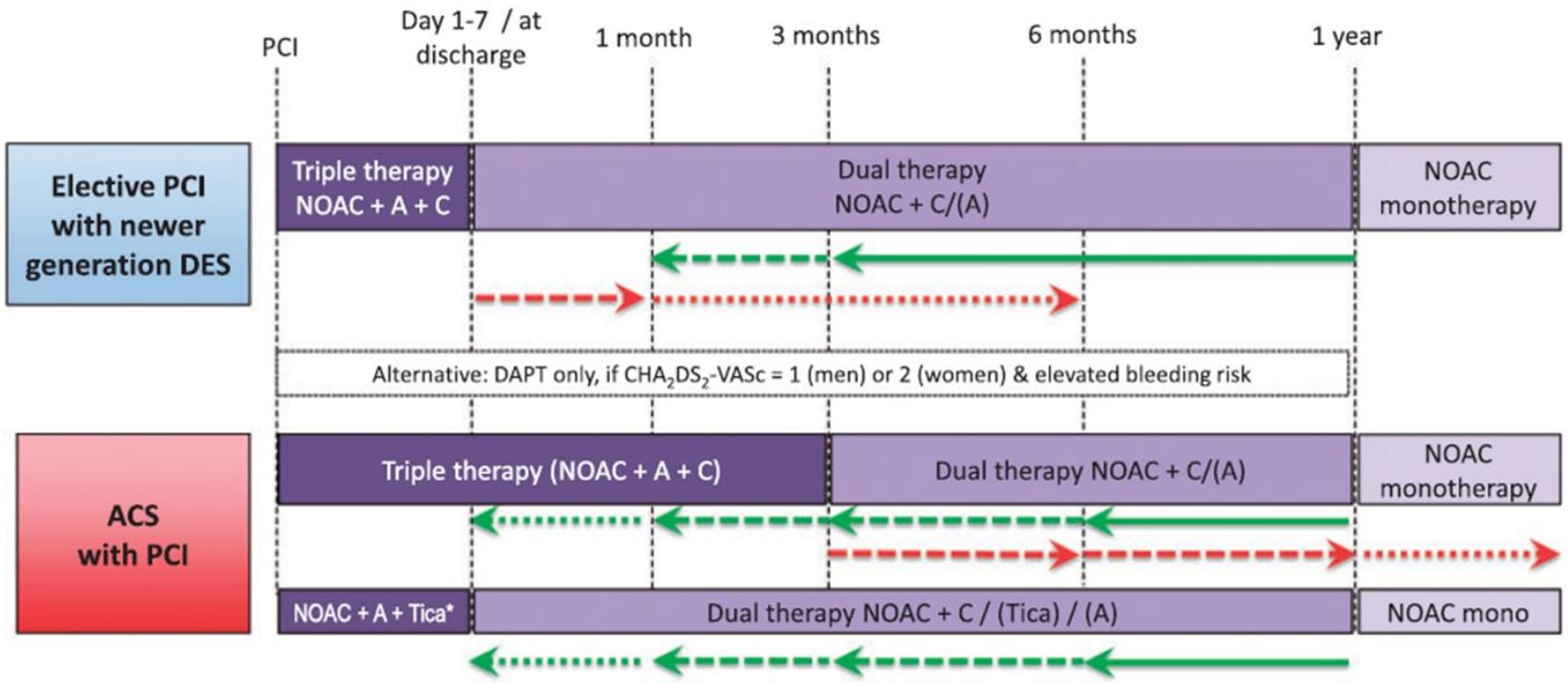
3 Monate DAPT (Klasse IIa)

1 Monat DAPT (Klasse IIb)



Leitlinien NSTEMI 2020: Class IIa

Thrombozytenaggregationshemmung nach PCI
+ Indikation zur Antikoagulation



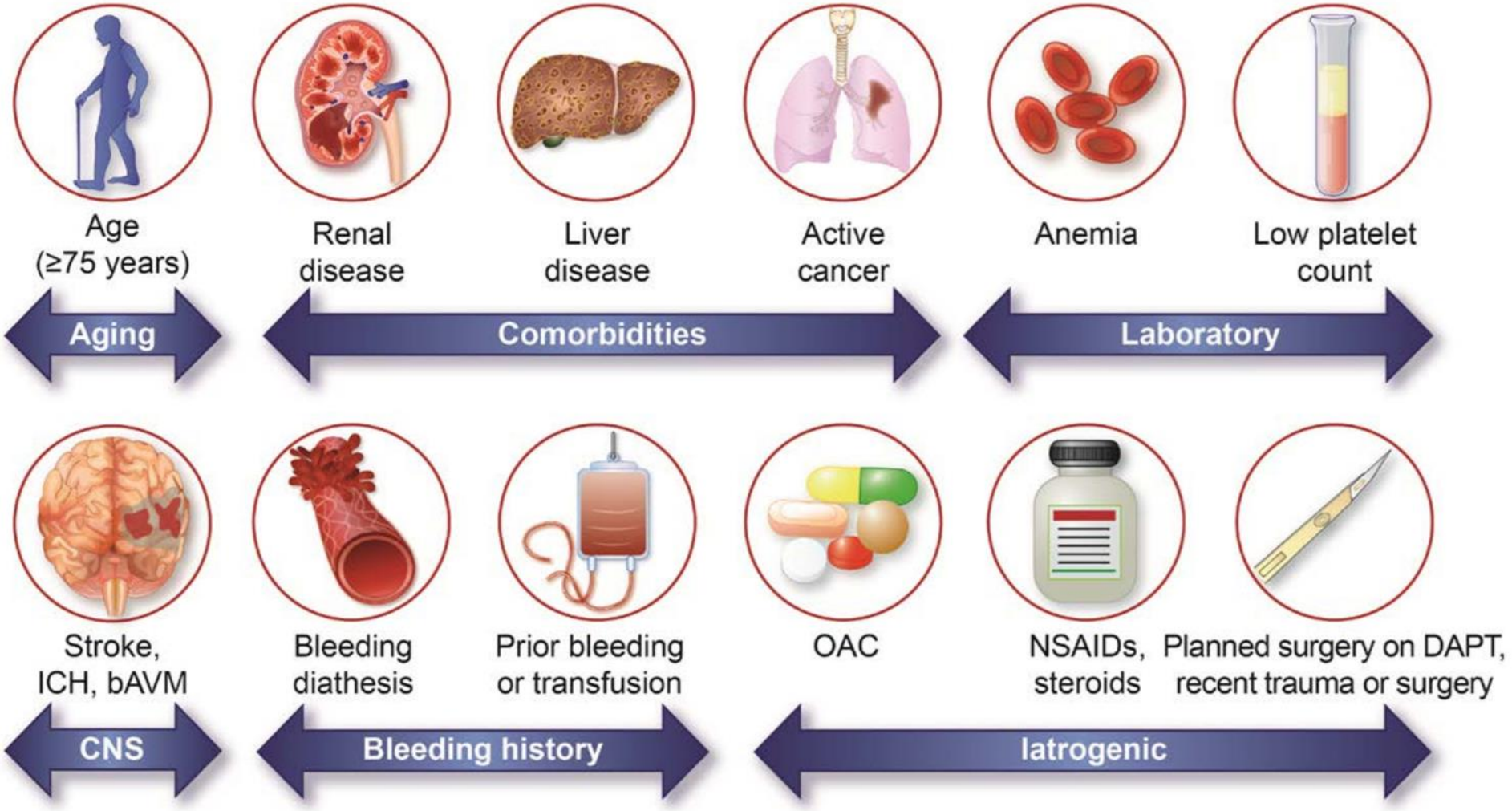
Factors to shorten combination therapy

- (Uncorrectable) high bleeding risk
- Low atherothrombotic risk (by REACH or SYNTAX score if elective; GRACE ≥140 if ACS)

Factors to lengthen combination therapy

- First-generation DES
- High atherothrombotic risk (scores as above ; stenting of the left main, proximal LAD, proximal bifurcation; recurrent MIs; stent thrombosis etc.) and low bleeding risk

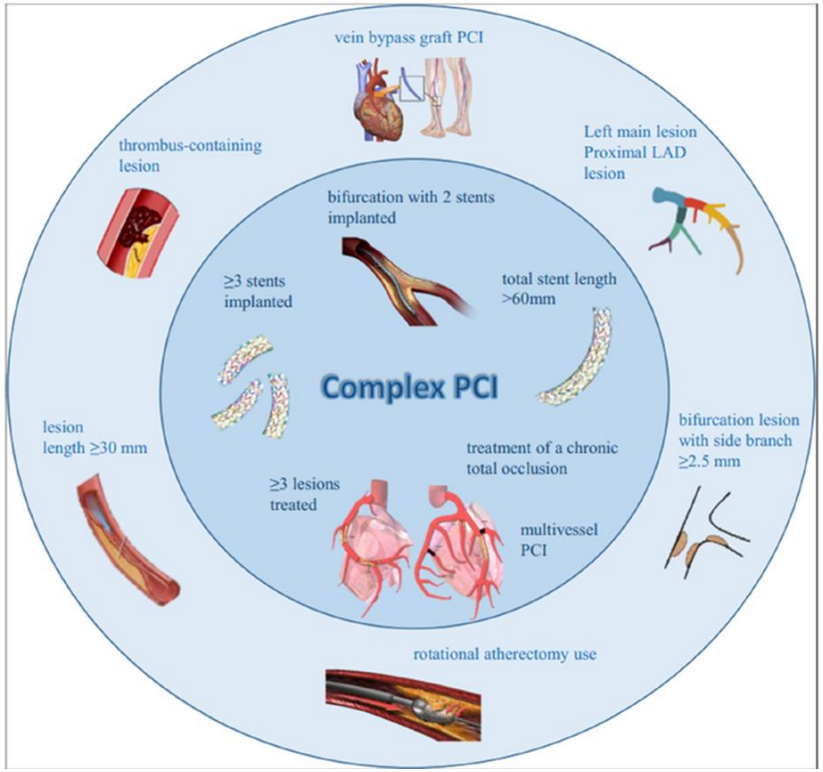
Blutungsrisiko - Faktoren



Urban et al. 2019. Circulation 140:240–261

Ischämierisiko - Faktoren

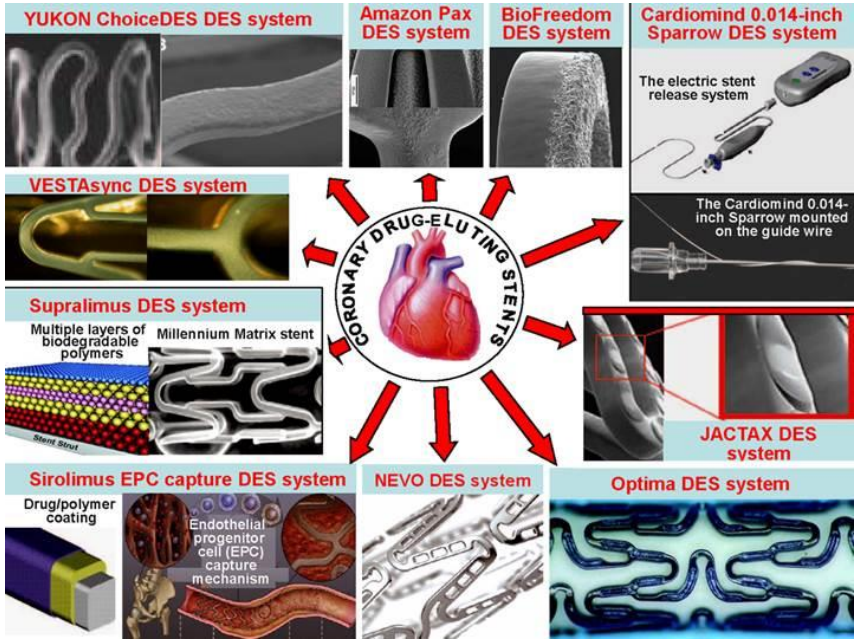
- Z.n. In-Stent Thrombose unter adäquater Thrombozytenaggregationshemmung
- Stent in das „last remaining vessel“
- Diffuse Mehrgefäßerkrankung, besonders bei Diabetes oder chron. Niereninsuff.
- mindestens 3 Stents implantiert
- mindestens 3 Läsionen behandelt
- Bifurkations-PCI mit 2 Stents
- Stentlänge (total) > 60 mm
- PCI einer CTO
- Z.n. STEMI



aus: Valgimigli et al. 2018. Eur Heart J. ESC Focused Update on DAPT.
und Benetou et al. 2020. Cardiovascular Drugs and Therapy 34:697–706

Stentaufbau mit möglichem Einfluss auf DAPT Dauer

Theranostics 2014; 4(2):175-200. doi:10.7150/thno.7210



~~**Bare Metal Stents** - Koronarstents aus blankem Metall~~

Drug Eluting Stents (DES) – Metall + Polymer + Medikament (Zytostatikum)

BP-DES Metall mit resorbierbarer Biopolymerschicht (+Medikament)

Bioresorbierbare Stents –nur spezielles Polymer (Magesium, Laktat) + Med., löst sich schließlich vollständig im Körper auf

Drug-coated Stents (DCS) : Metall + Medikament, ohne Polymer

Dual-Therapie-Stent : Metall + resorbierbares Biopolymer + Medikament + Anitkörper

- Zytostatikum um neointimale Hyperplasie zu hemmen
- anti-CD34 Antikörper (nur luminale Seite), um endotheliale Stammzellen „einzufangen“

Endpunkte in Herz-Kreislaufstudien

MACE – Major Adverse Cardiovascular Event(s)

- Tod
- (Re-)Myokardinfarkt
- erneute PCI
- Schlaganfall

NACE – Net Adverse Clinical Event(s)

NACCE – NET ADVERSE CLINICAL **AND CEREBRAL** EVENTS

NACE = MACE + schwere Blutung

(“major bleeding”, außer als Folge einer Bypass-OP)

MASTER DAPT Studie

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Dual Antiplatelet Therapy after PCI in Patients at High Bleeding Risk

M. Valgimigli, E. Frigoli, D. Heg, J. Tijssen, P. Jüni, P. Vranckx, Y. Ozaki, M.-C. Morice, B. Chevalier, Y. Onuma, S. Windecker, P.A.L. Tonino, M. Roffi, M. Lesiak, F. Mahfoud, J. Bartunek, D. Hildick-Smith, A. Colombo, G. Stanković, A. Iñiguez, C. Schultz, R. Kornowski, P.J.L. Ong, M. Alasnag, A.E. Rodriguez, A. Moschovitis, P. Laanmets, M. Donahue, S. Leonardi, and P.C. Smits, for the MASTER DAPT Investigators*

This article was published on August 28, 2021, at NEJM.org.

MASTER DAPT Studie

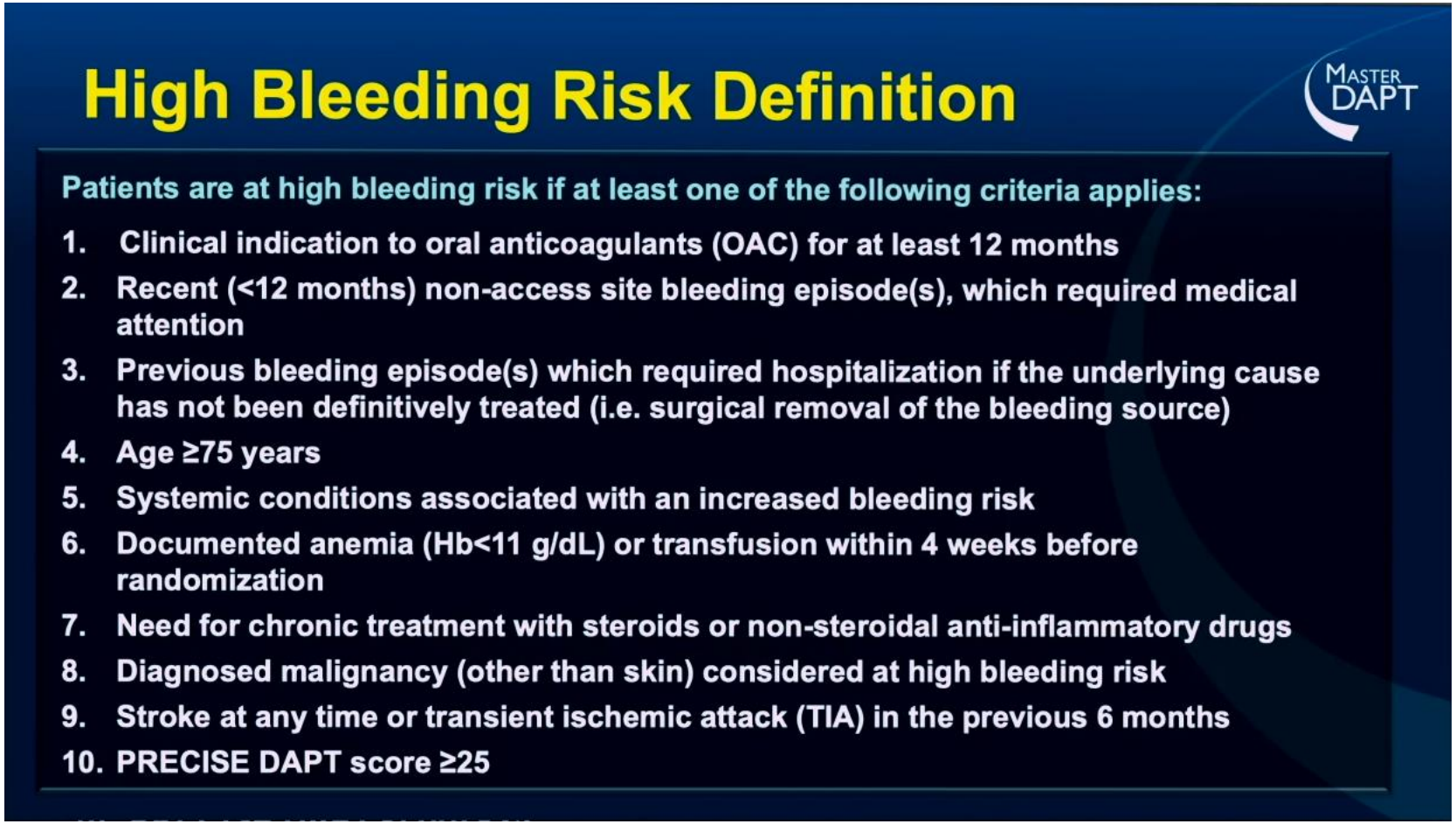
verwendeter Stent

BP-DES Metall mit resorbierbarer Biopolymerschicht (+Sirolimus)

MASTER DAPT Studie

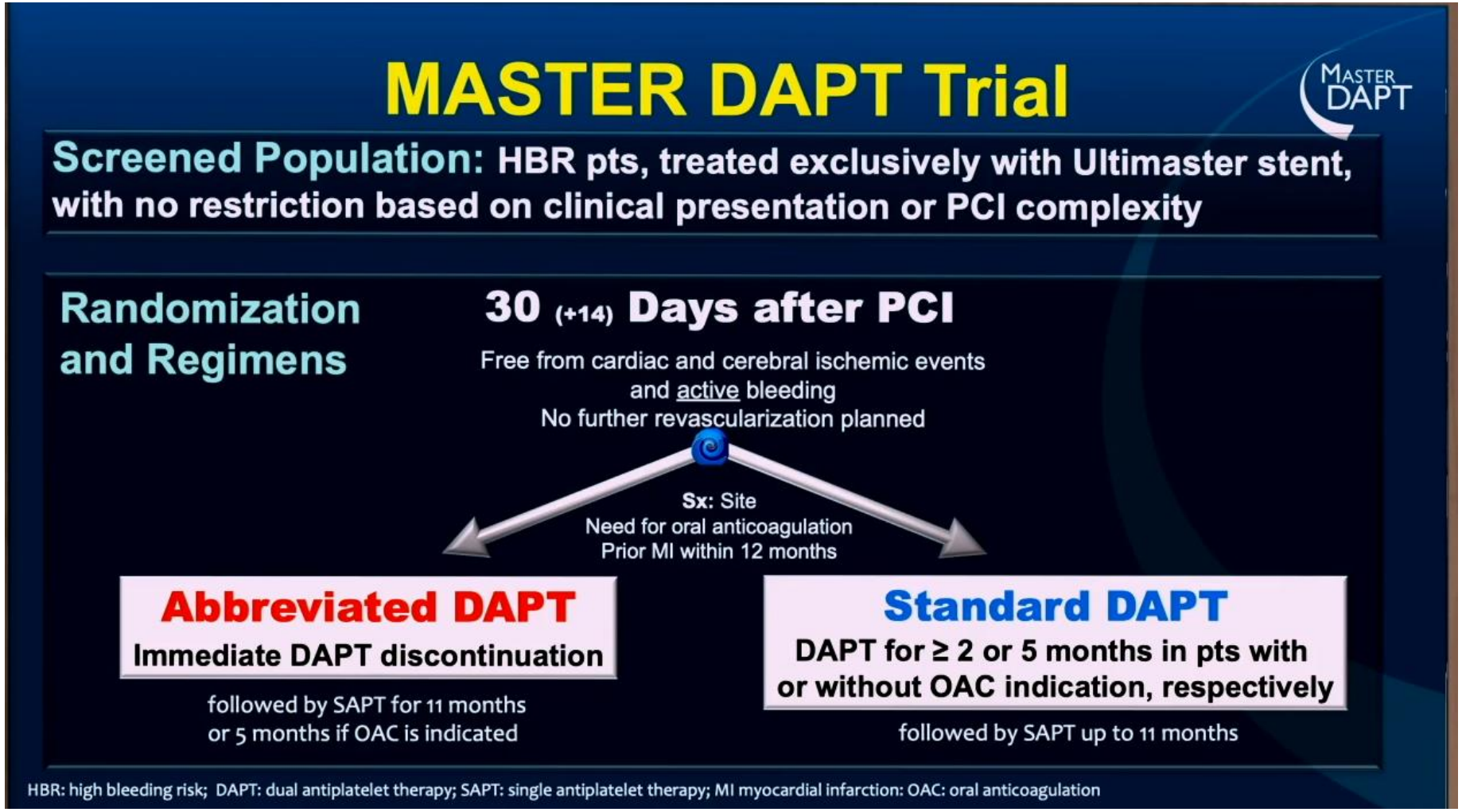
<u>Einschluss :</u>
Z.n. ACS + erfolgr. PCI
oder CAD + erfolgr. PCI

… sowie erhöhtes
Risiko für Blutungen

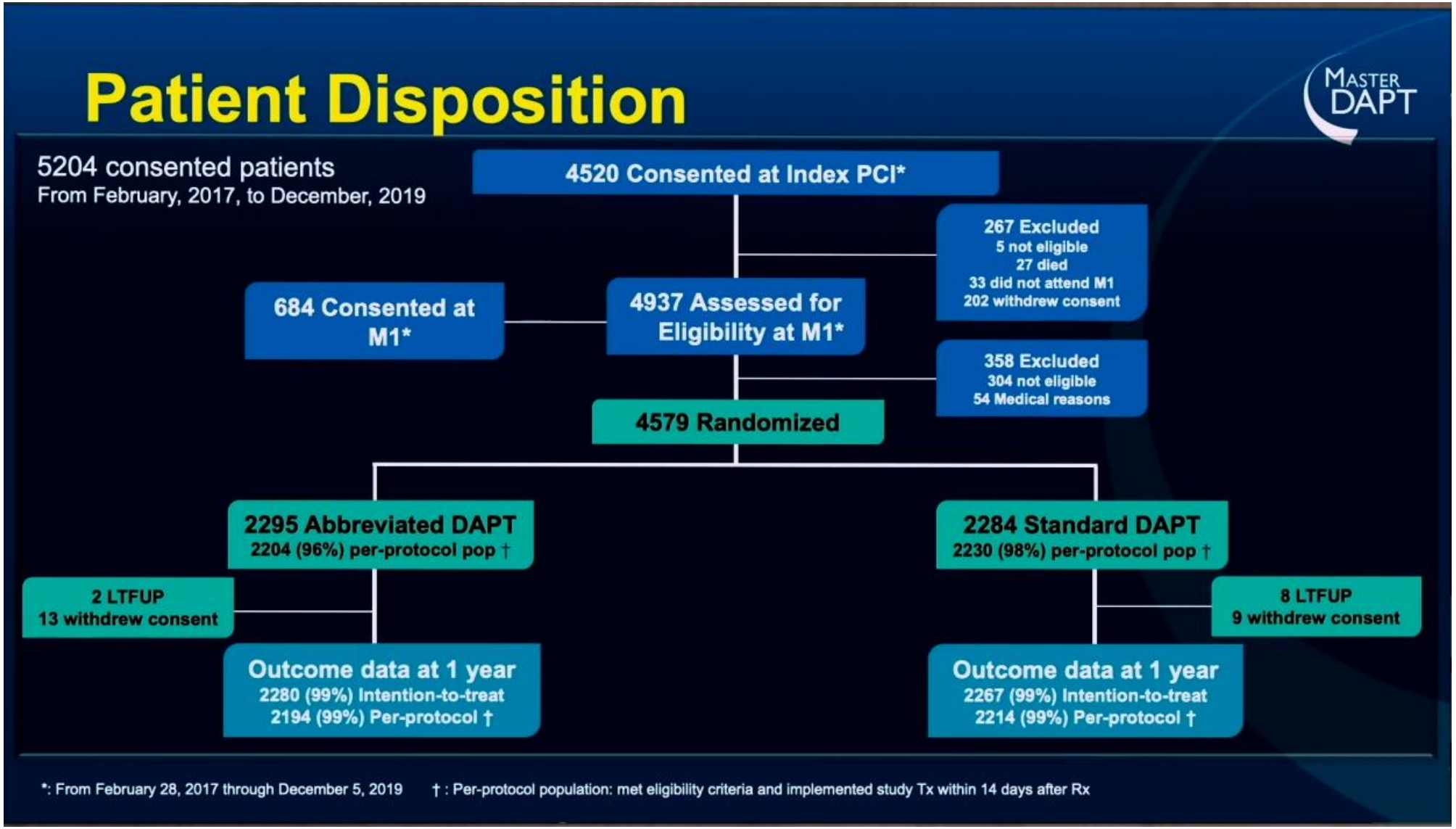


MASTER DAPT Studie

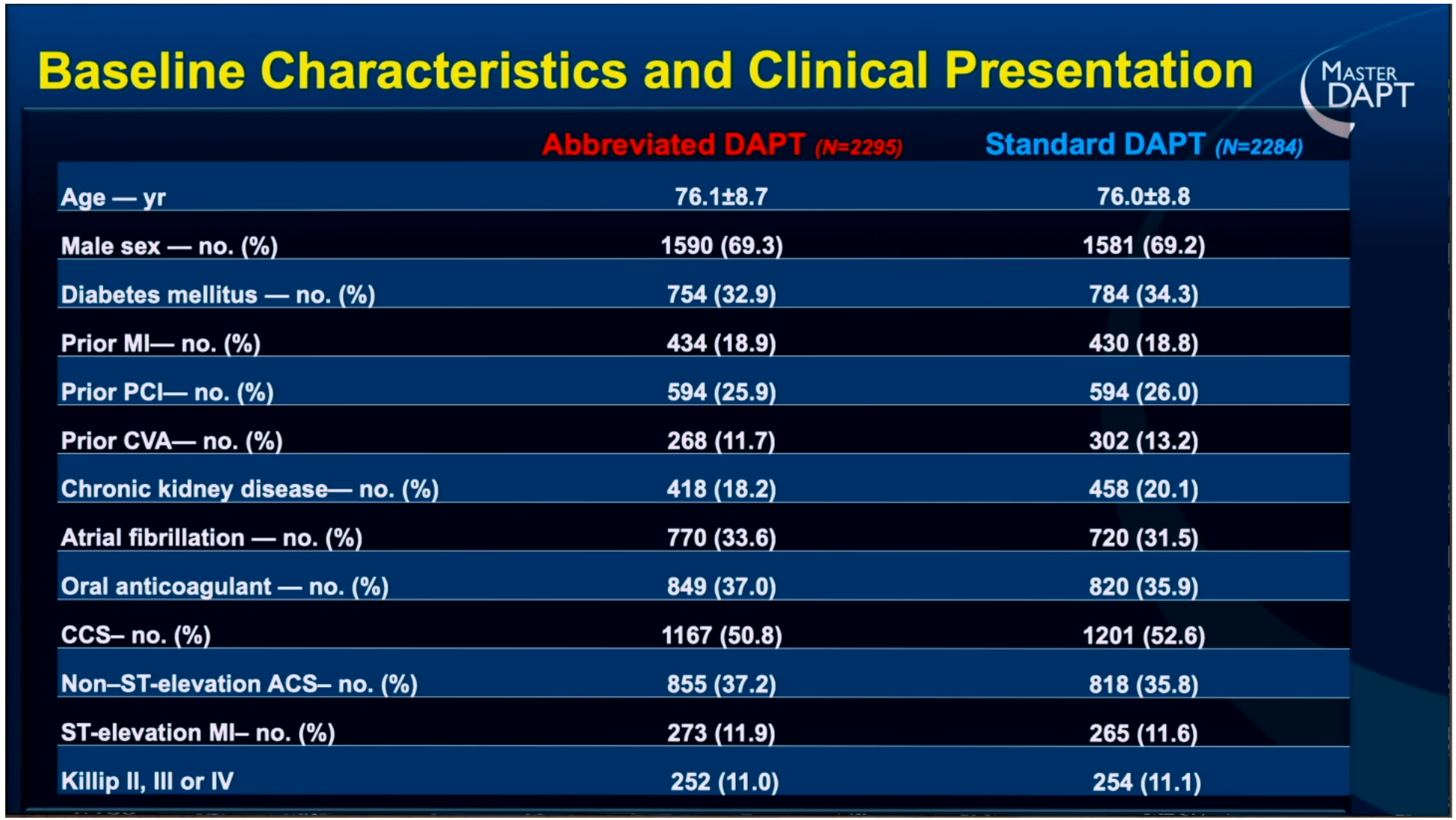
Einschluss :
erst nach Abschluß
von 30d DAPT



MASTER DAPT Studie

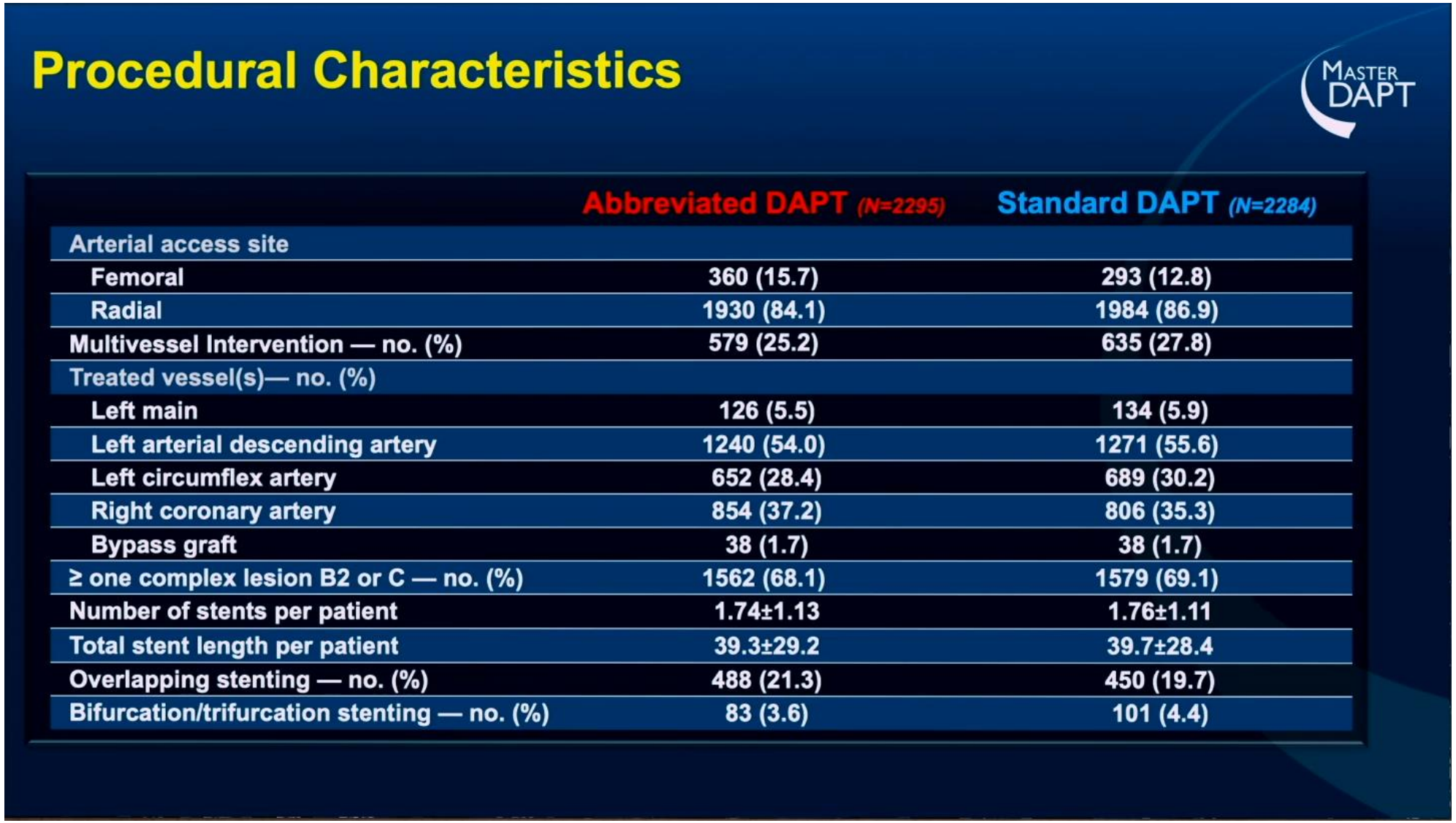


MASTER DAPT Studie



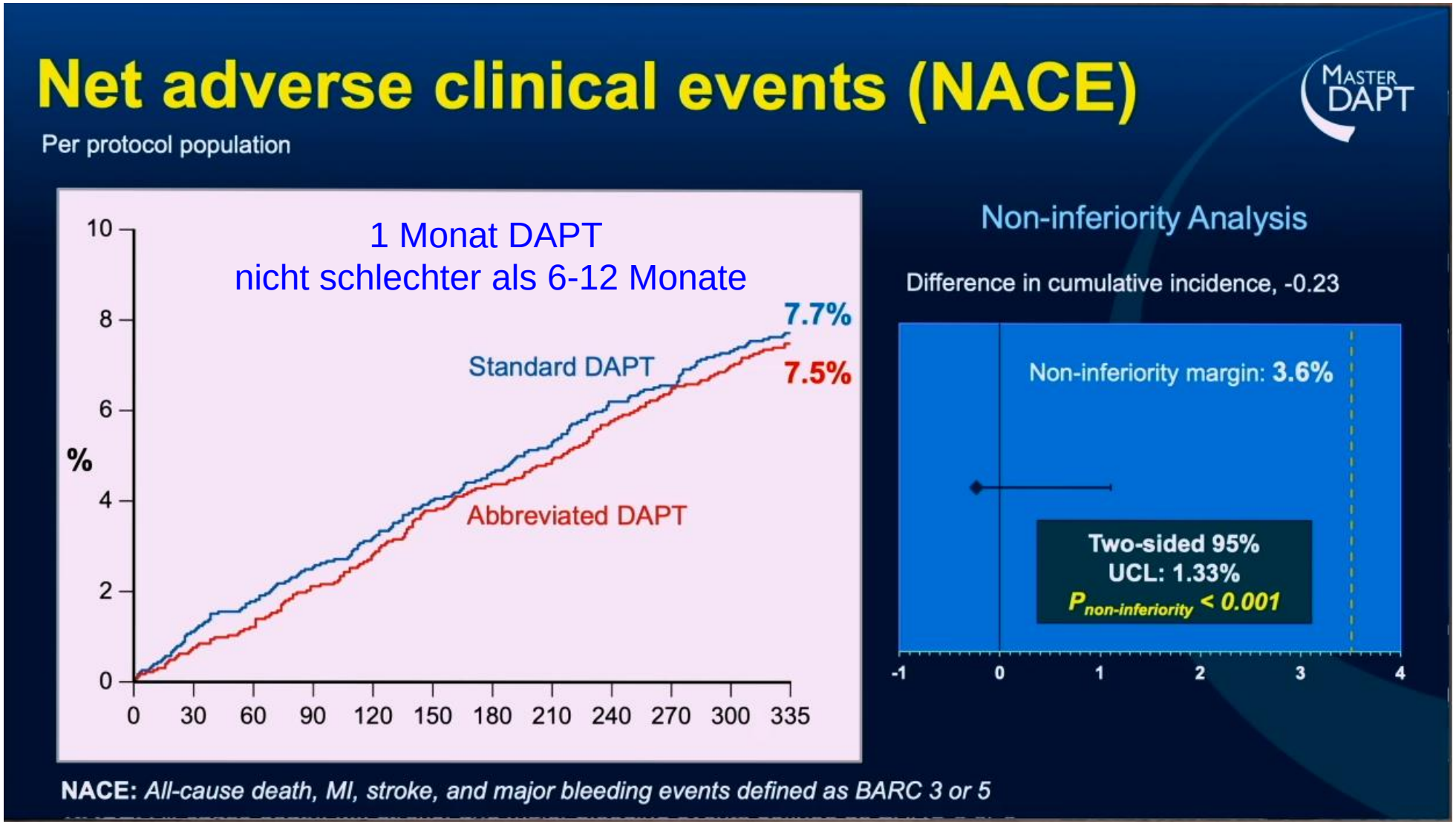
	Abbreviated DAPT (N=2295)	Standard DAPT (N=2284)
Age — yr	76.1±8.7	76.0±8.8
Male sex — no. (%)	1590 (69.3)	1581 (69.2)
Diabetes mellitus — no. (%)	754 (32.9)	784 (34.3)
Prior MI— no. (%)	434 (18.9)	430 (18.8)
Prior PCI— no. (%)	594 (25.9)	594 (26.0)
Prior CVA— no. (%)	268 (11.7)	302 (13.2)
Chronic kidney disease— no. (%)	418 (18.2)	458 (20.1)
Atrial fibrillation — no. (%)	770 (33.6)	720 (31.5)
Oral anticoagulant — no. (%)	849 (37.0)	820 (35.9)
CCS– no. (%)	1167 (50.8)	1201 (52.6)
Non–ST-elevation ACS– no. (%)	855 (37.2)	818 (35.8)
ST-elevation MI– no. (%)	273 (11.9)	265 (11.6)
Killip II, III or IV	252 (11.0)	254 (11.1)

MASTER DAPT Studie

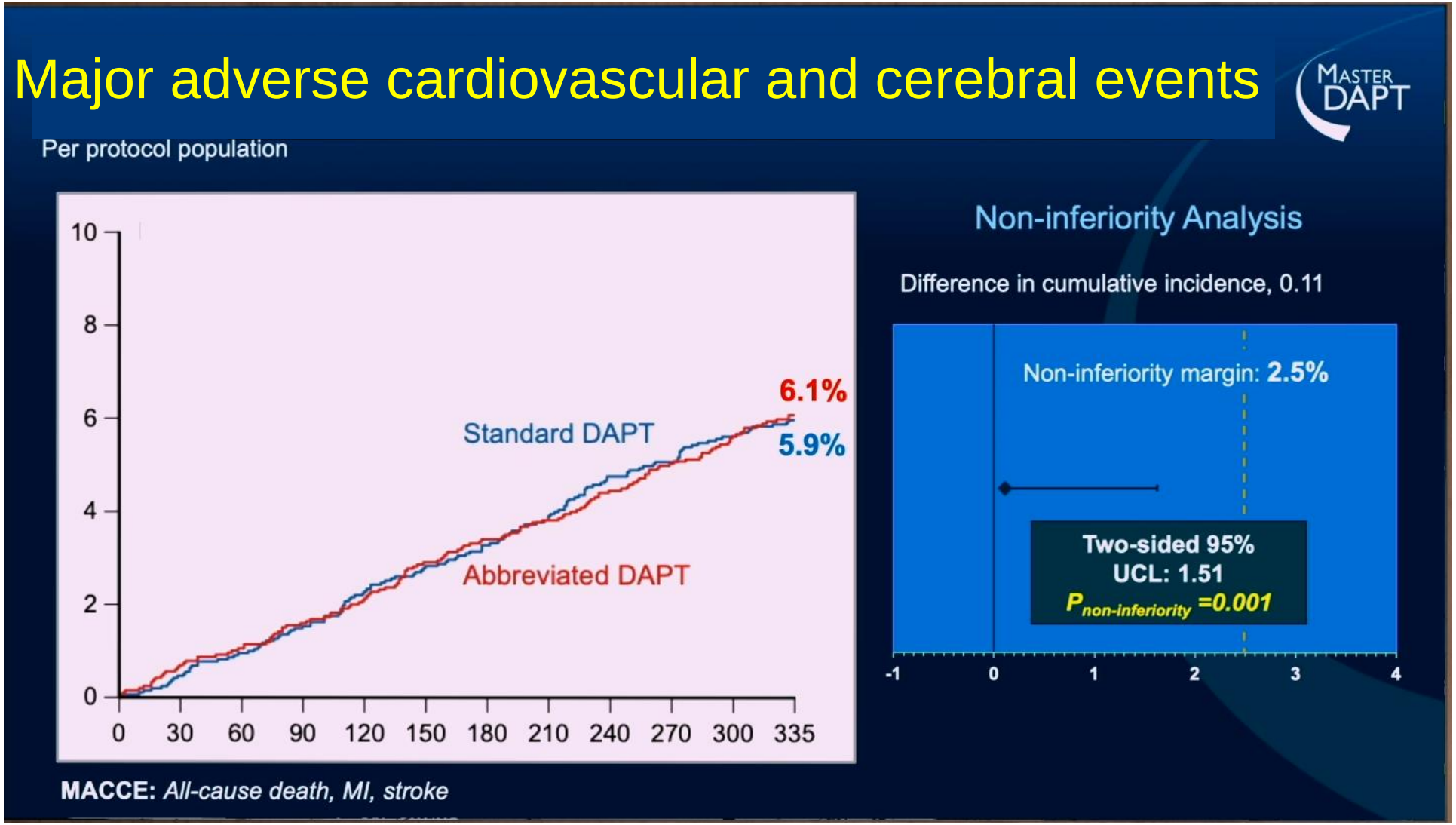


	Abbreviated DAPT (N=2295)	Standard DAPT (N=2284)
Arterial access site		
Femoral	360 (15.7)	293 (12.8)
Radial	1930 (84.1)	1984 (86.9)
Multivessel Intervention — no. (%)	579 (25.2)	635 (27.8)
Treated vessel(s)— no. (%)		
Left main	126 (5.5)	134 (5.9)
Left arterial descending artery	1240 (54.0)	1271 (55.6)
Left circumflex artery	652 (28.4)	689 (30.2)
Right coronary artery	854 (37.2)	806 (35.3)
Bypass graft	38 (1.7)	38 (1.7)
≥ one complex lesion B2 or C — no. (%)	1562 (68.1)	1579 (69.1)
Number of stents per patient	1.74±1.13	1.76±1.11
Total stent length per patient	39.3±29.2	39.7±28.4
Overlapping stenting — no. (%)	488 (21.3)	450 (19.7)
Bifurcation/trifurcation stenting — no. (%)	83 (3.6)	101 (4.4)

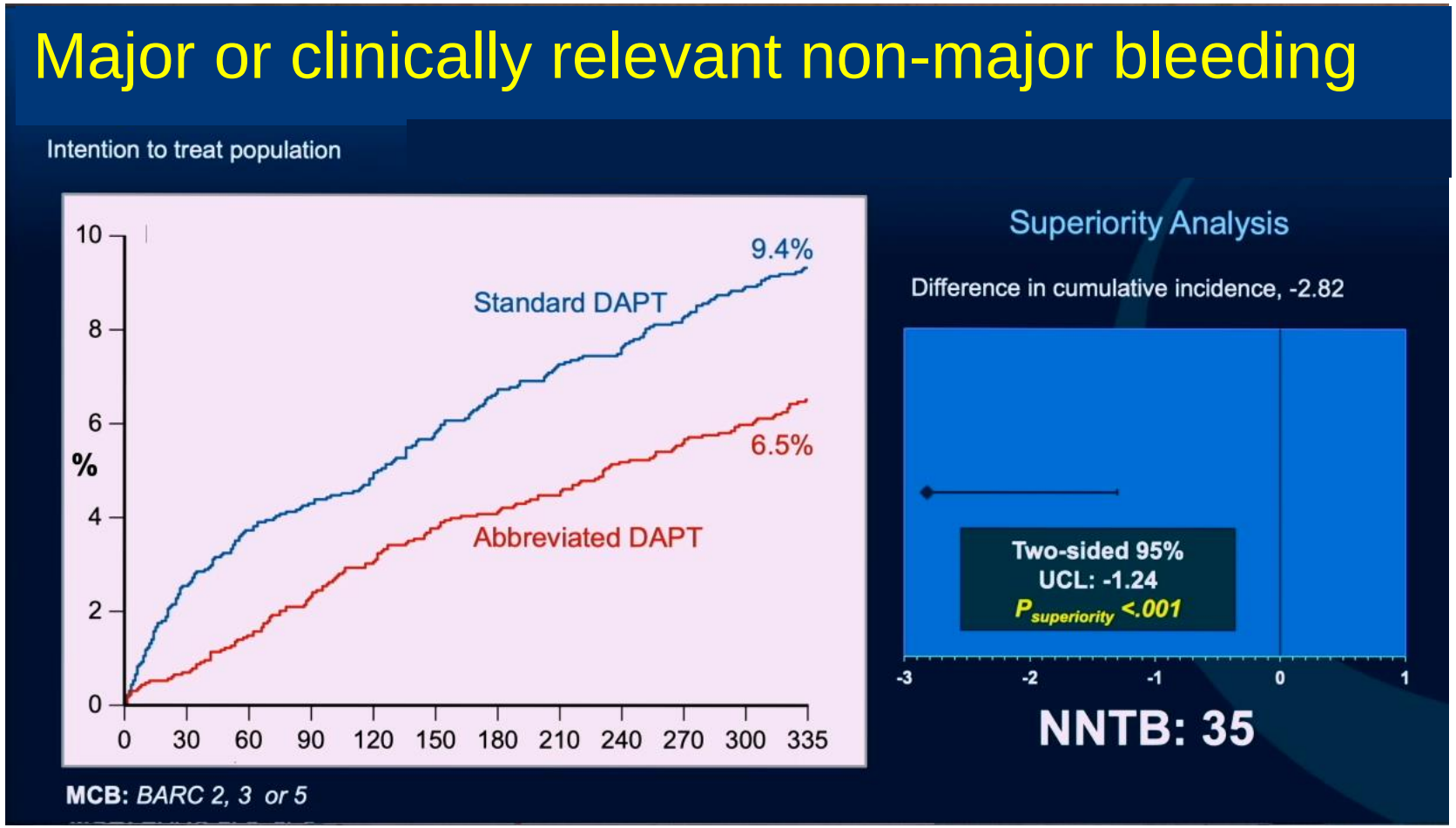
MASTER DAPT Studie



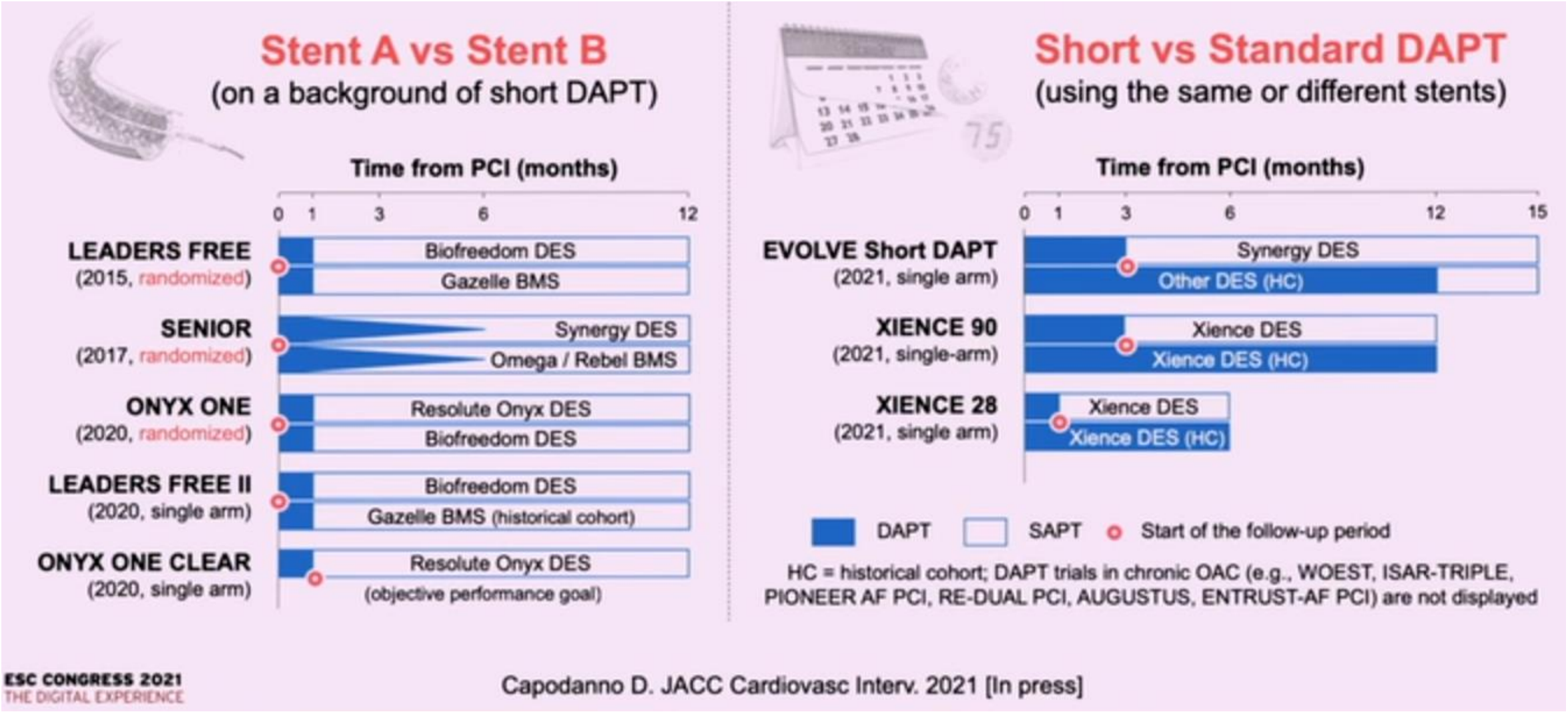
MASTER DAPT Studie



MASTER DAPT Studie



Bisherige Studien bei Patienten mit erhöhtem Blutungsrisiko



MASTER DAPT Studie

- Erste randomisierte, kontrollierte Studie
  zur Dauer der DAPT Therapie unabhängig von OAK

- Bei Patienten mit erhöhtem Blutungsrisiko, die nach 1 Monat DAPT keine Ereignisse hatten, kann es sinnvoll sein, die DAPT-Therapie dann schon zu beenden.

- Cave: Vergleichsgruppe hatte variable DAPT-Zeiten (6-12 Mo), und in der OAK Subgruppe war die Triple-Therapie relativ lang.

STOPDAPT 2 ACS

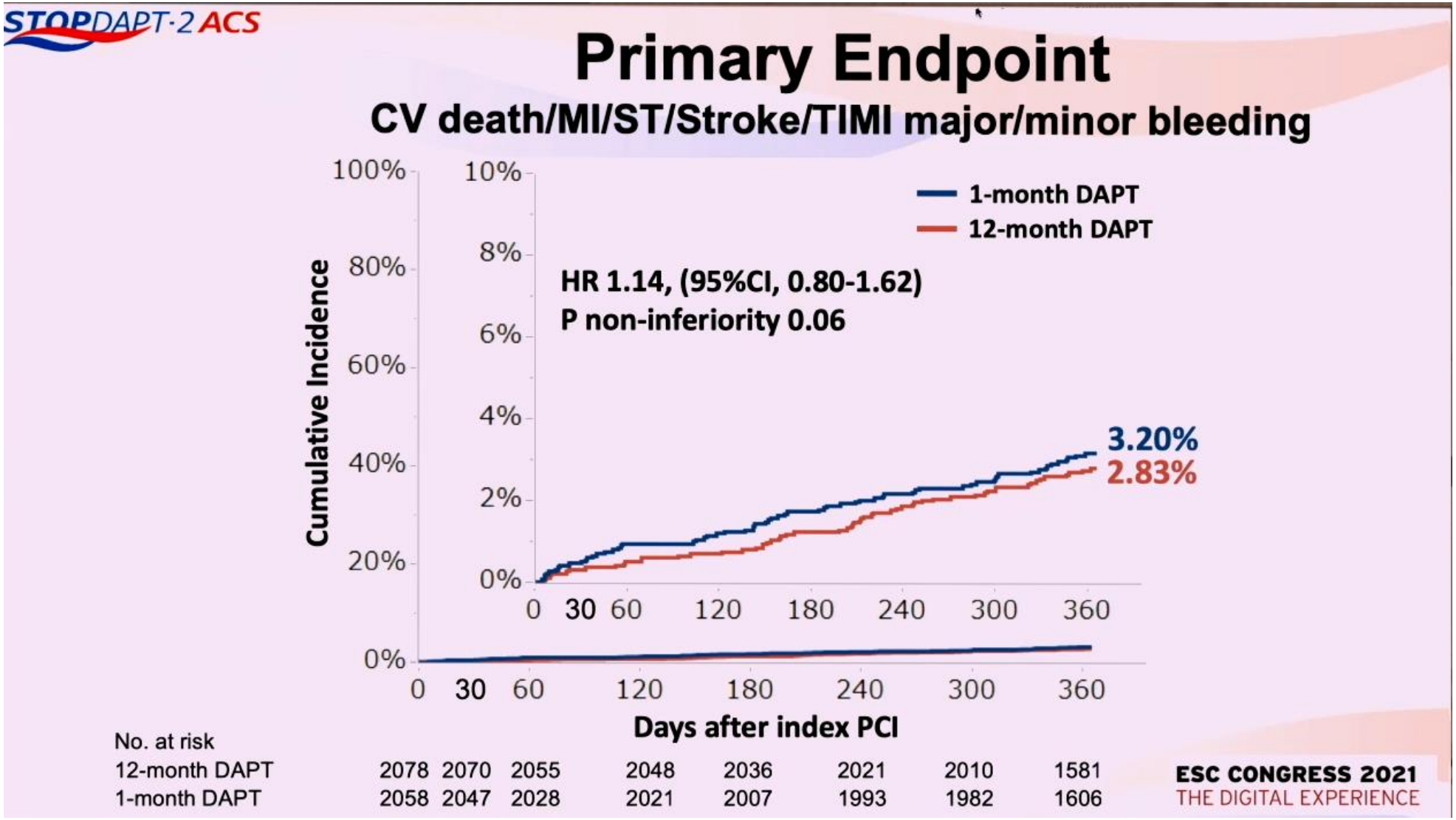
- Patienten mit PCI bei ACS

1 Monat DAPT (ASS+Clopidogrel), dann Clopidogrel

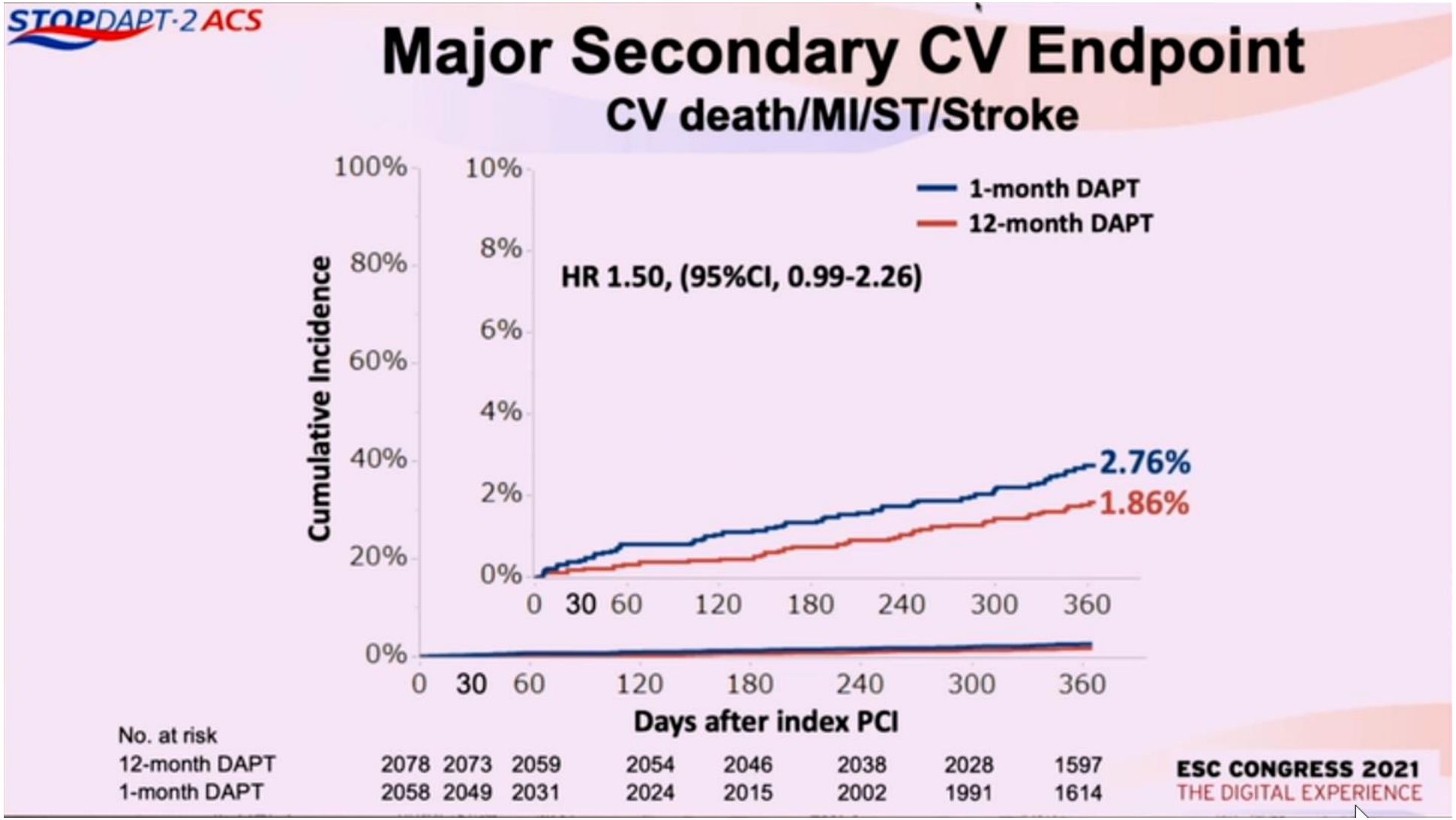
vs.

12 Monate DAPT

STOPDAPT 2 ACS



STOPDAPT 2 ACS

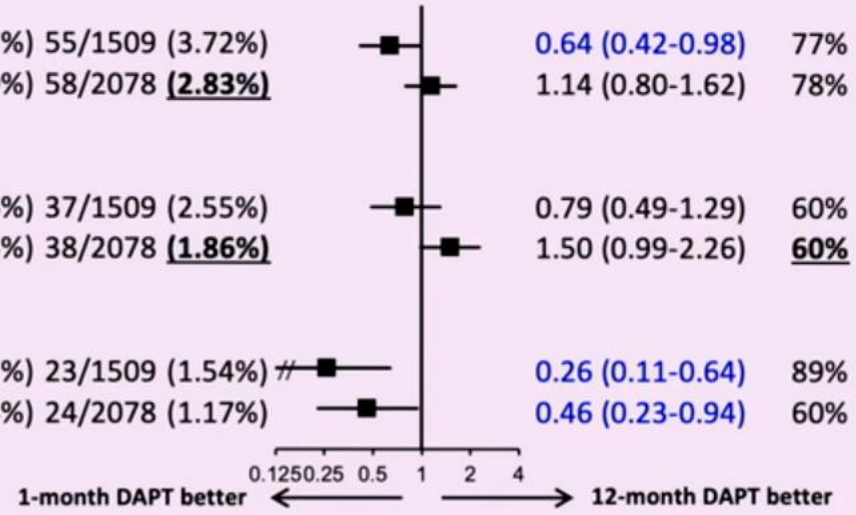


STOPDAPT 2 vs. STOPDAPT 2 ACS

STOPDAPT-2 ACS

Comparison between STOPDAPT-2 and STOPDAPT-2 ACS

	N of event/Total (incidence %) 1-month DAPT	12-month DAPT	HR (95%CI)	Post-hoc actual stat. power*
Primary endpoint				
STOPDAPT-2 (N=3009)	35/1500 (2.37%)	55/1509 (3.72%)	0.64 (0.42-0.98)	77%
Present study (N=4136)	65/2058 (3.20%)	58/2078 **(2.83%)**	1.14 (0.80-1.62)	78%
Major secondary CV endpoint				
STOPDAPT-2	29/1500 (1.96%)	37/1509 (2.55%)	0.79 (0.49-1.29)	60%
Present study	56/2058 (2.76%)	38/2078 **(1.86%)**	1.50 (0.99-2.26)	**60%**
Major secondary Bleeding endpoint				
STOPDAPT-2	6/1500 (0.41%)	23/1509 (1.54%)	0.26 (0.11-0.64)	89%
Present study	11/2058 (0.54%)	24/2078 (1.17%)	0.46 (0.23-0.94)	60%



*Power calculated from actual event rate of 12-month DAPT group: Power for non-inferiority analysis of 1-month DAPT with HR 1.5 in the primary and major secondary CV endpoints, and power for superiority analysis of 1-month DAPT in the major secondary bleeding endpoint with observed risk reduction .

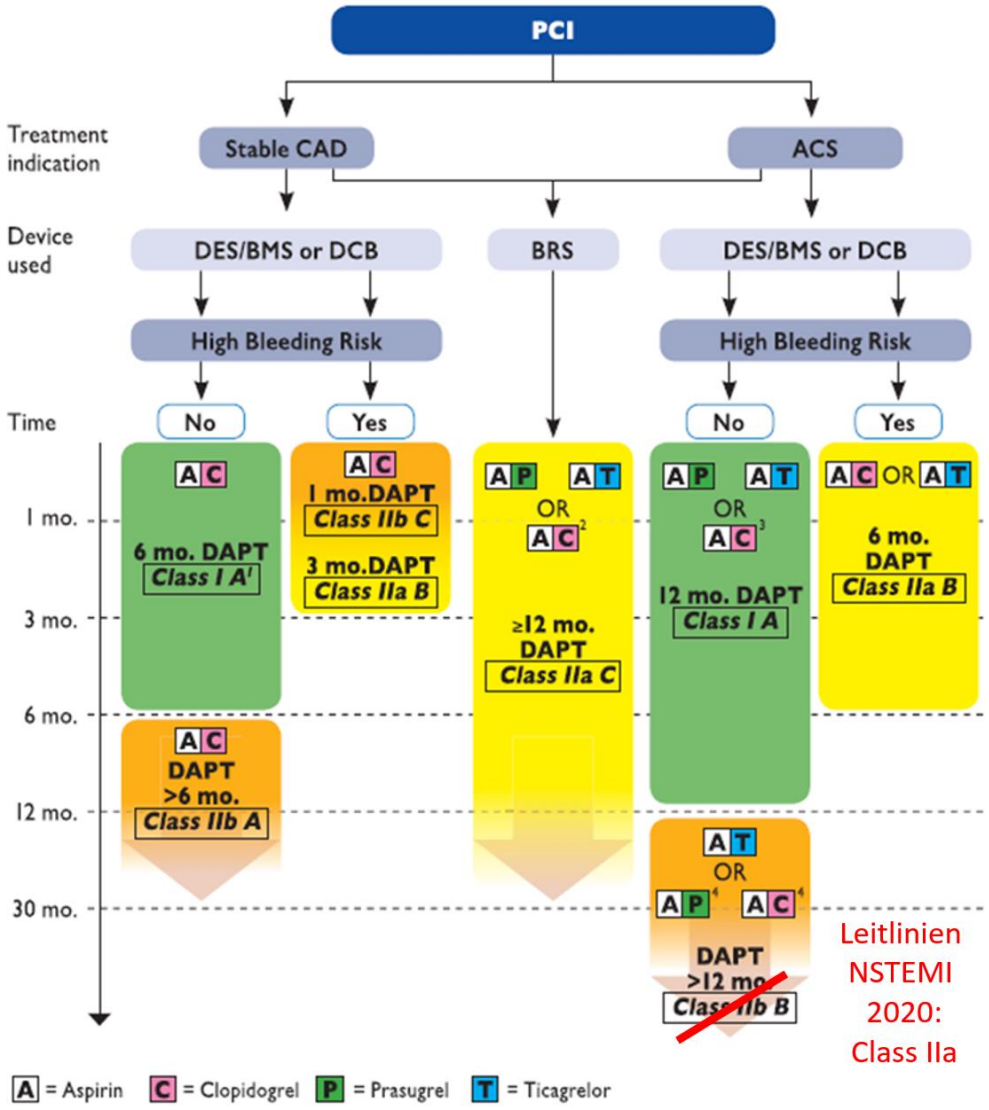
Thrombozytenaggregationshemmung nach PCI

… je nach Blutungsrisiko (und Stent-Typ)

6 Monate DAPT (Klasse I Empfehlung)

3 Monate DAPT (Klasse IIa)

1 Monat DAPT (Klasse IIb)



Leitlinien NSTEMI 2020: Class IIa