



GESTIONE
PERIOPERATORIA
DEI PAZIENTI
IN TERAPIA
ANTITROMBOTICA
"BRIDGING THERAPY"

TORINO, 7 Ottobre 2016

Nuovi stents a rapida endotelizzazione: quando ed in quali pazienti

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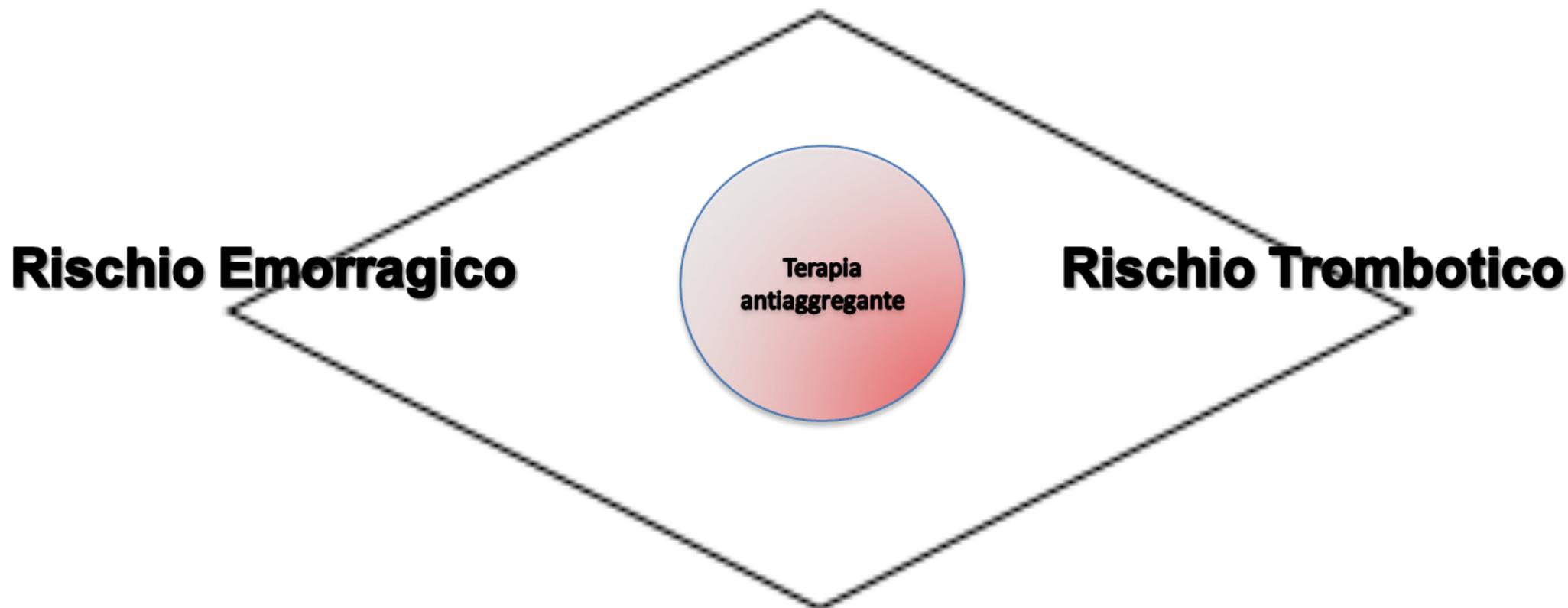
Clinical update

Optimal duration of dual antiplatelet therapy after drug-eluting stent implantation: conceptual evolution based on emerging evidence

La scelta della **corretta durata** della duplice terapia
antiaggregante dopo rivascolarizzazione percutanea
rappresenta una delle principali sfide della cardiologia
interventistica.

Durata terapia antiaggregante dopo rivascularizzazione coronarica percutanea

Presentazione Clinica
(sindromi coronariche acute vs. malattia stabile)



Scelta del Device
(stent metallici, stent medicati, scaffold riassorbibili)

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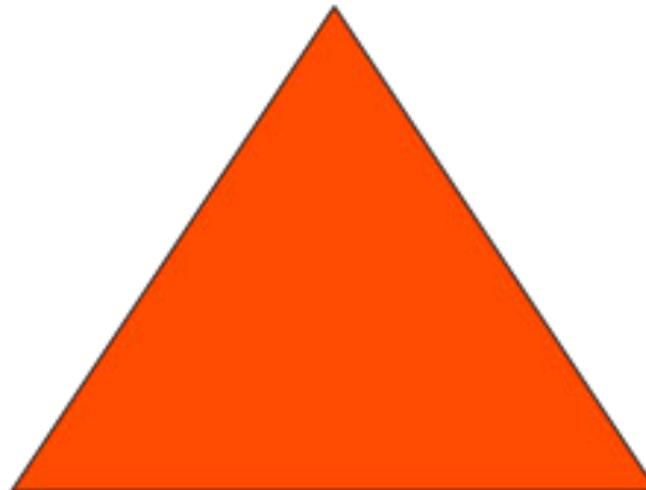


Balancing ischaemia and bleeding with dual antiplatelet therapy: a resolute endeavour

Gregg W. Stone*

**Eventi
cardiovascolari**

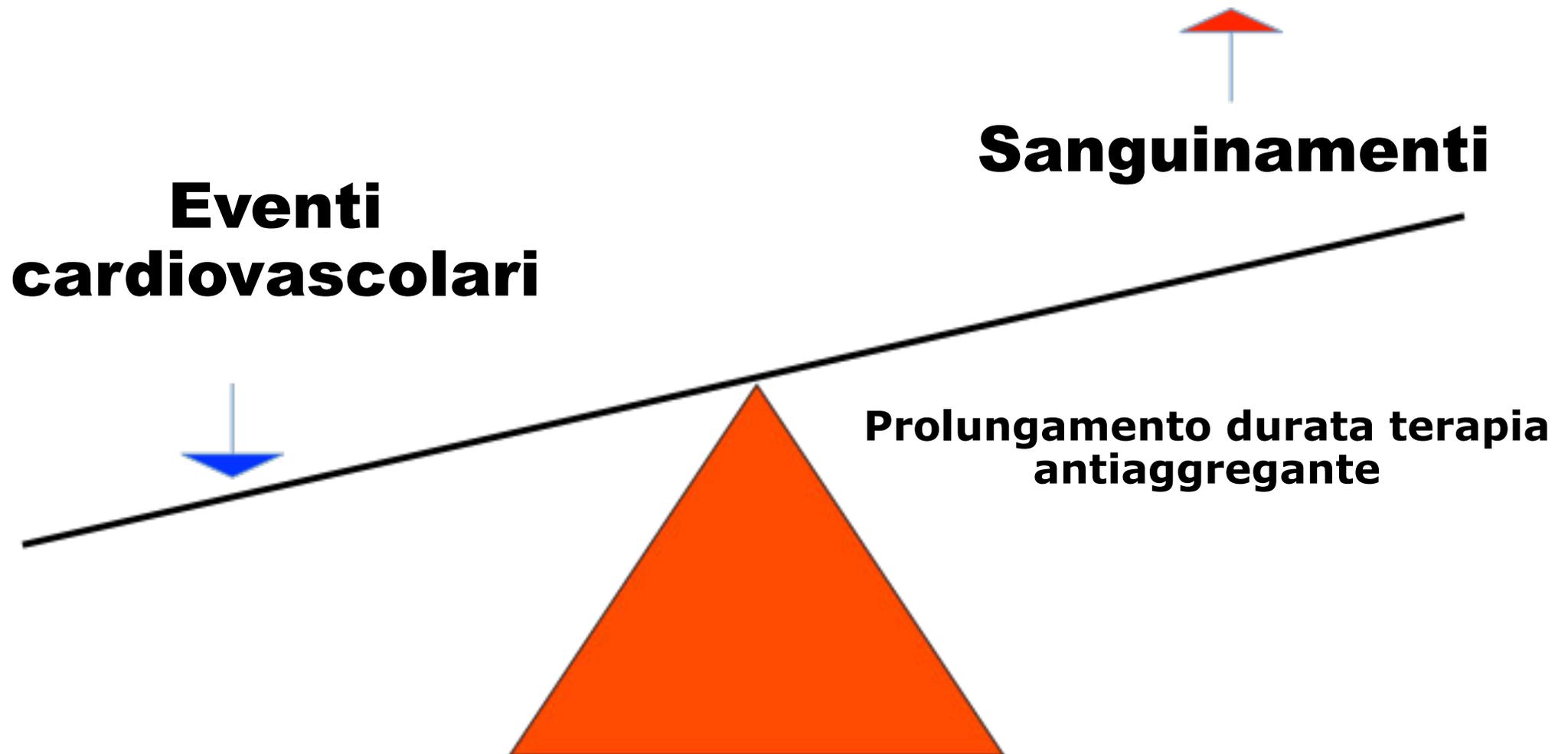
Sanguinamenti





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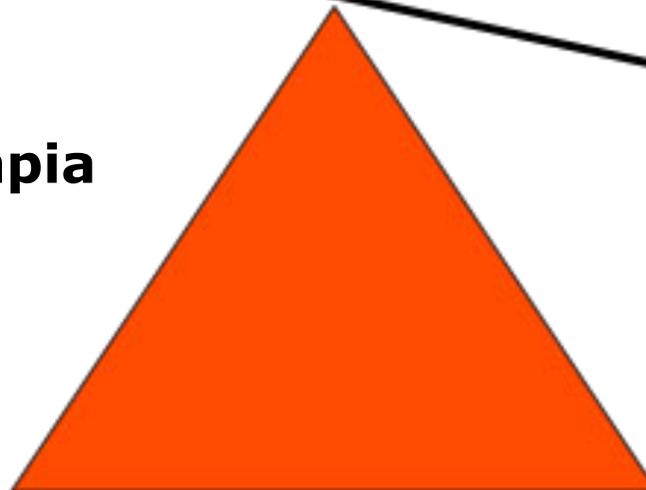


**Eventi
cardiovascolari**



Sanguinamenti

**Riduzione durata terapia
antiaggregante**

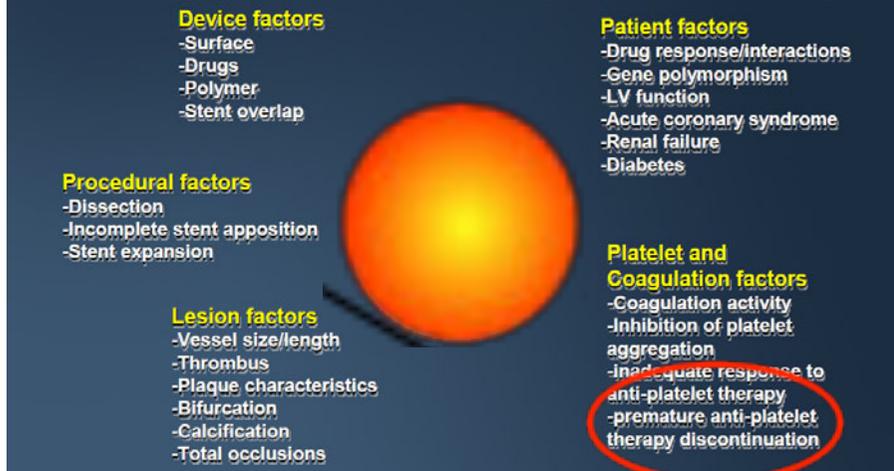


Stent Thrombosis

Multifactorial Nature of DES Thrombosis

Trombosi di stent:

- Incidenza di infarto miocardico acuto del 80-90%
- Morte del 20-30%

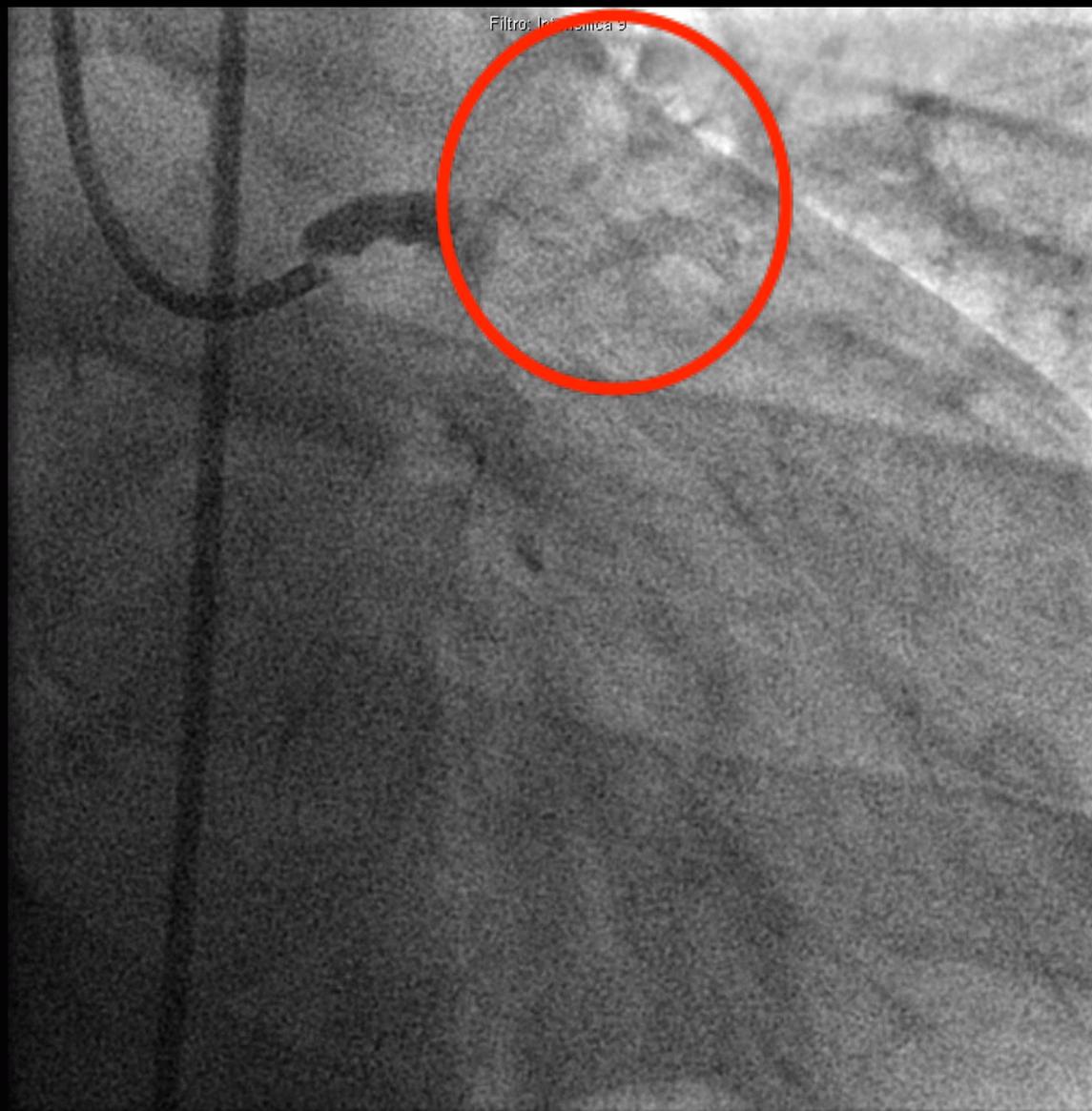


Stent
Thrombosis

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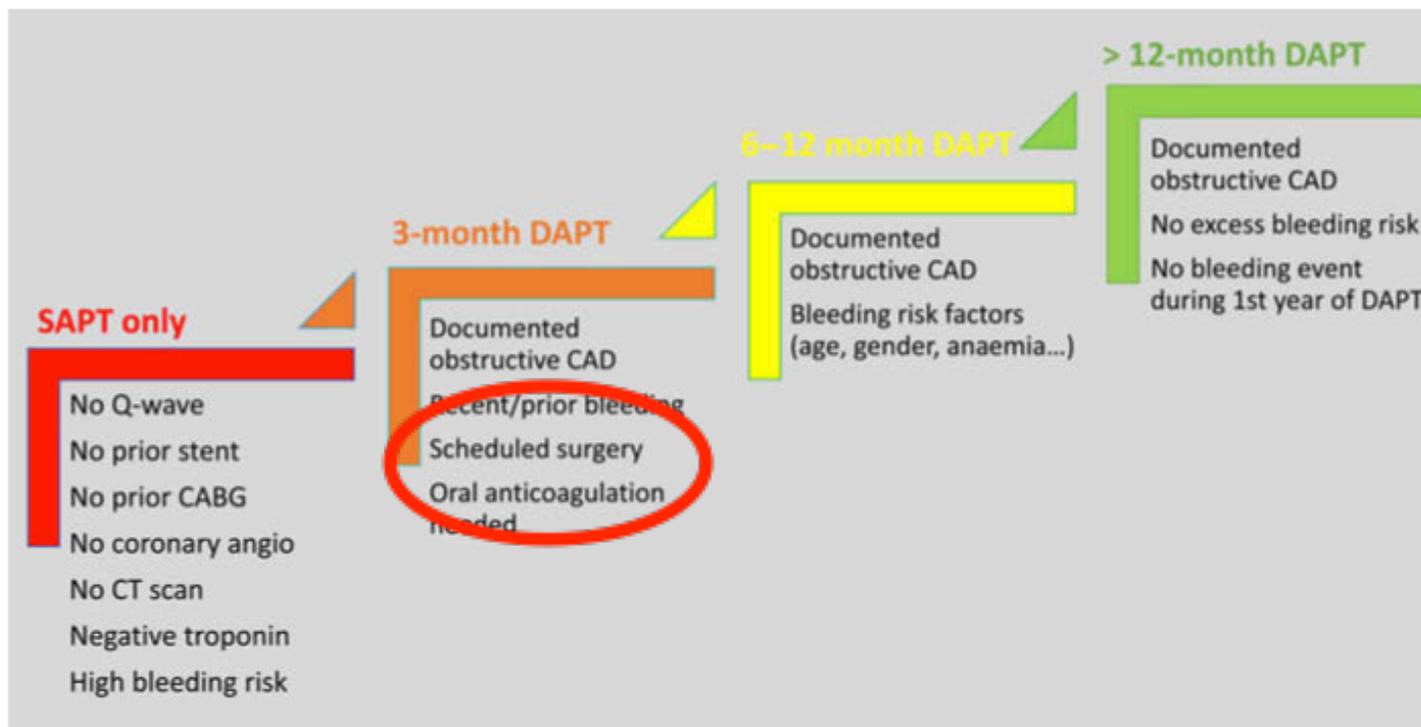
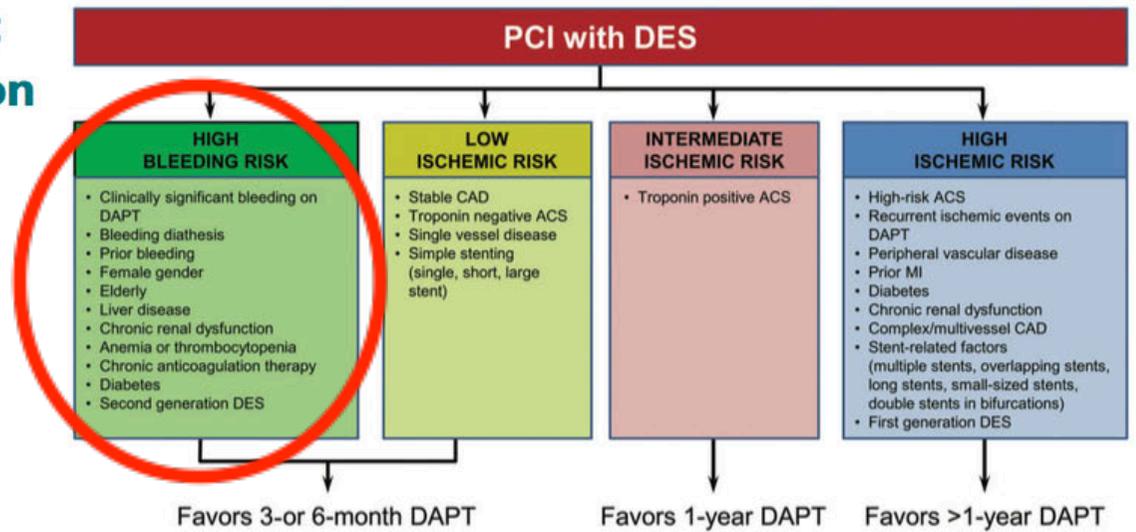
Nuovi stents a rapida endotelizzazione:
quando ed in quali pazienti

Stent Thrombosis



Nuovi stents a rapida endotelizzazione:
quando ed in quali pazienti

The search for optimal dual antiplatelet therapy after PCI: fine-tuning of initiation and duration



2014 ESC/EACTS Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Shorter DAPT duration (<6 months) may be considered after DES implantation in patients at high bleeding risk.

IIb

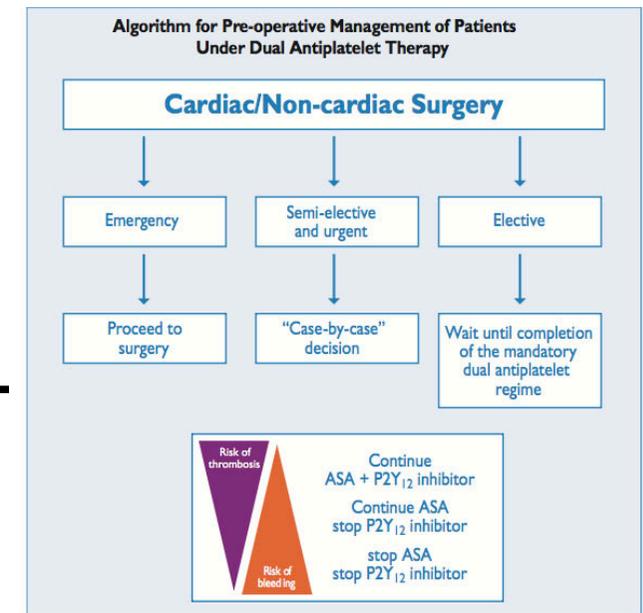
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BMS

BARE METAL STENT

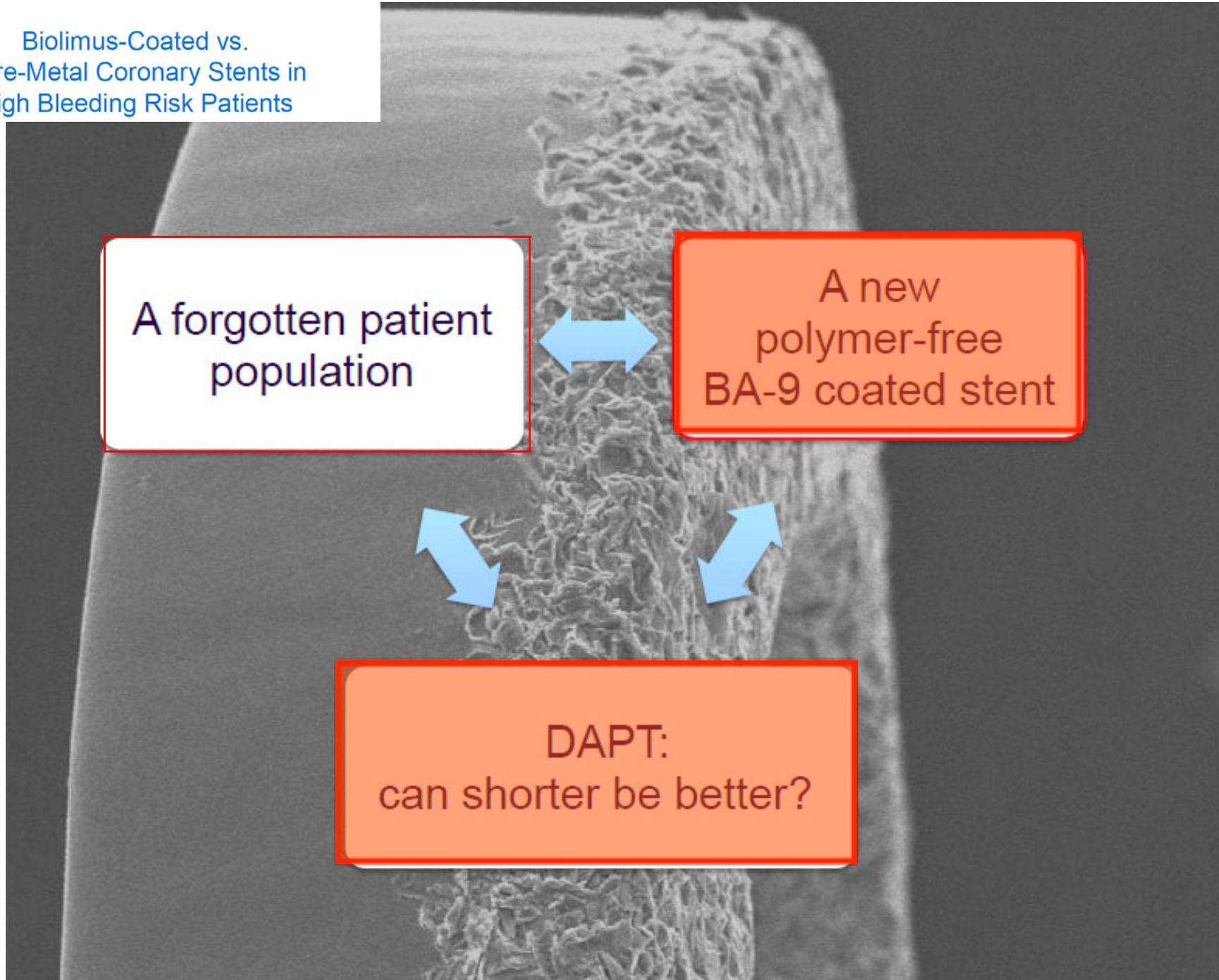


Biolimus-Coated vs.
Bare-Metal Coronary Stents in
High Bleeding Risk Patients

A forgotten patient
population

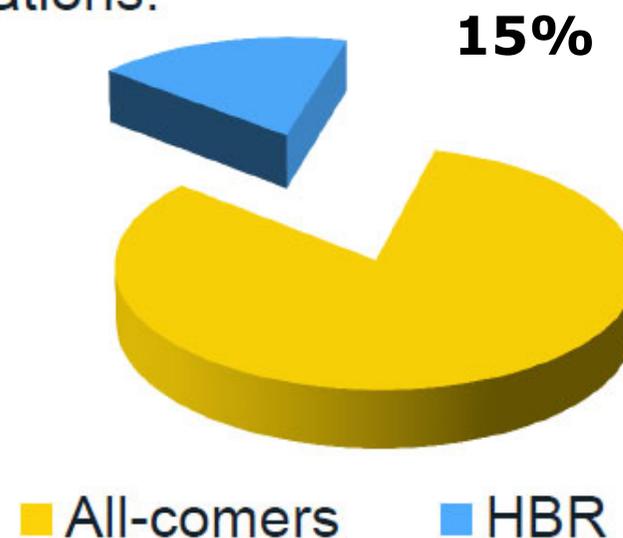
A new
polymer-free
BA-9 coated stent

DAPT:
can shorter be better?

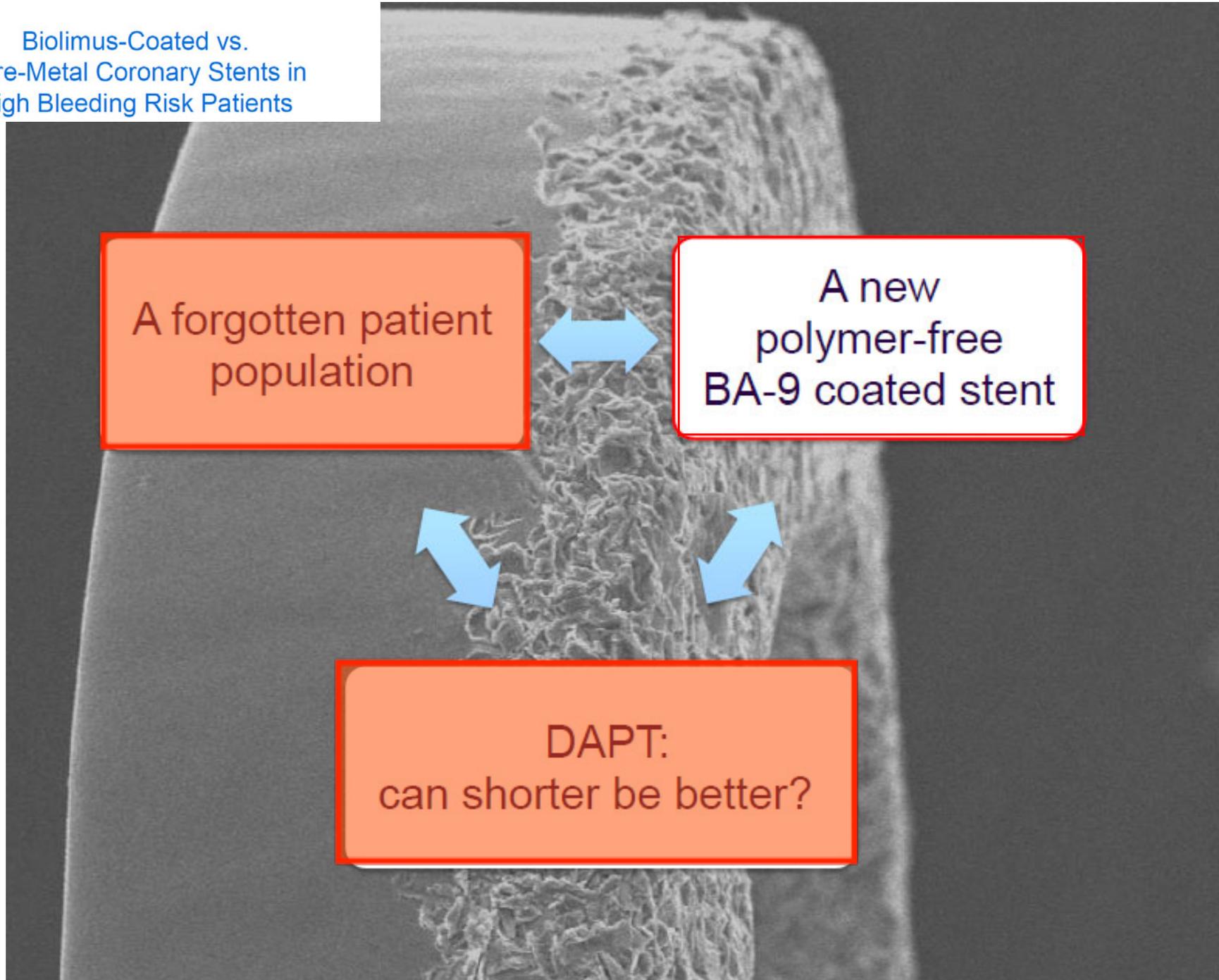


High Bleeding Risk Patients (HBR)

- Mostly excluded from device and APT trials
- Never specifically studied
- Current guideline recommendations:
 - BMS + one month DAPT
 - DES + “shortened” DAPT



Biolimus-Coated vs.
Bare-Metal Coronary Stents in
High Bleeding Risk Patients



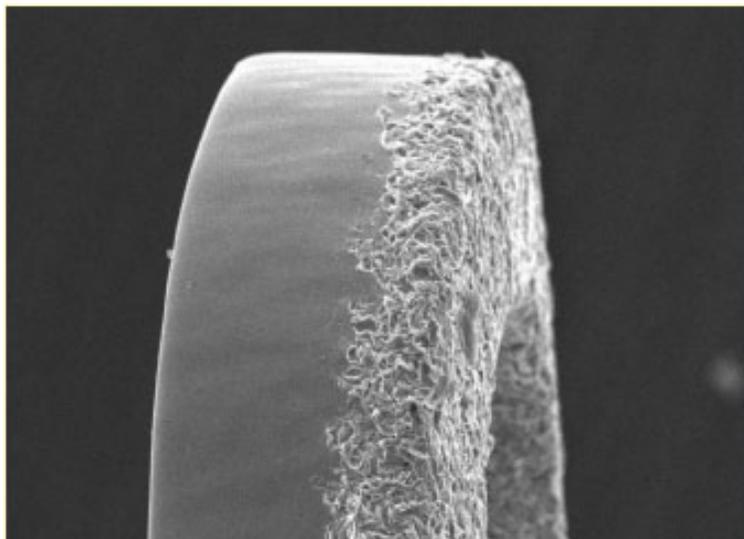
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DAPT:
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BioFreedom™ Drug Coated Stent (DCS)

Selectively micro-structured surface holds drug in abluminal surface structures



The Selectively Micro-structured Surface (SMS) Retains the BA9 Drug...

SMS is only applied to the abluminal surface of the BioFreedom stent, allowing BA9 to be contained on the micro-structured surface and delivered in a **uniform dose** to the target lesion. The combined benefit of SMS and BA9 allow drug delivery without the need for a polymer or carrier making BioFreedom a true DCS

BA9 Drug Delivered Only Where it Matters

As only the abluminal surface of the stent is SMS treated, BA9 is delivered exactly where it's needed, at the target lesion site in the vessel wall.

Promotes Rapid Re-endothelialization

By leaving a bare metal stent luminal surface and therefore removing potential sources of inflammation that delay or interrupt re-endothelialisation, BioFreedom promotes rapid re-endothelialization and the healing process.*



STENT PLATFORM



SMS TREATMENT (ABLUMINAL SURFACE)



DCS BA9 APPLICATION DIRECTLY ON THE STENT



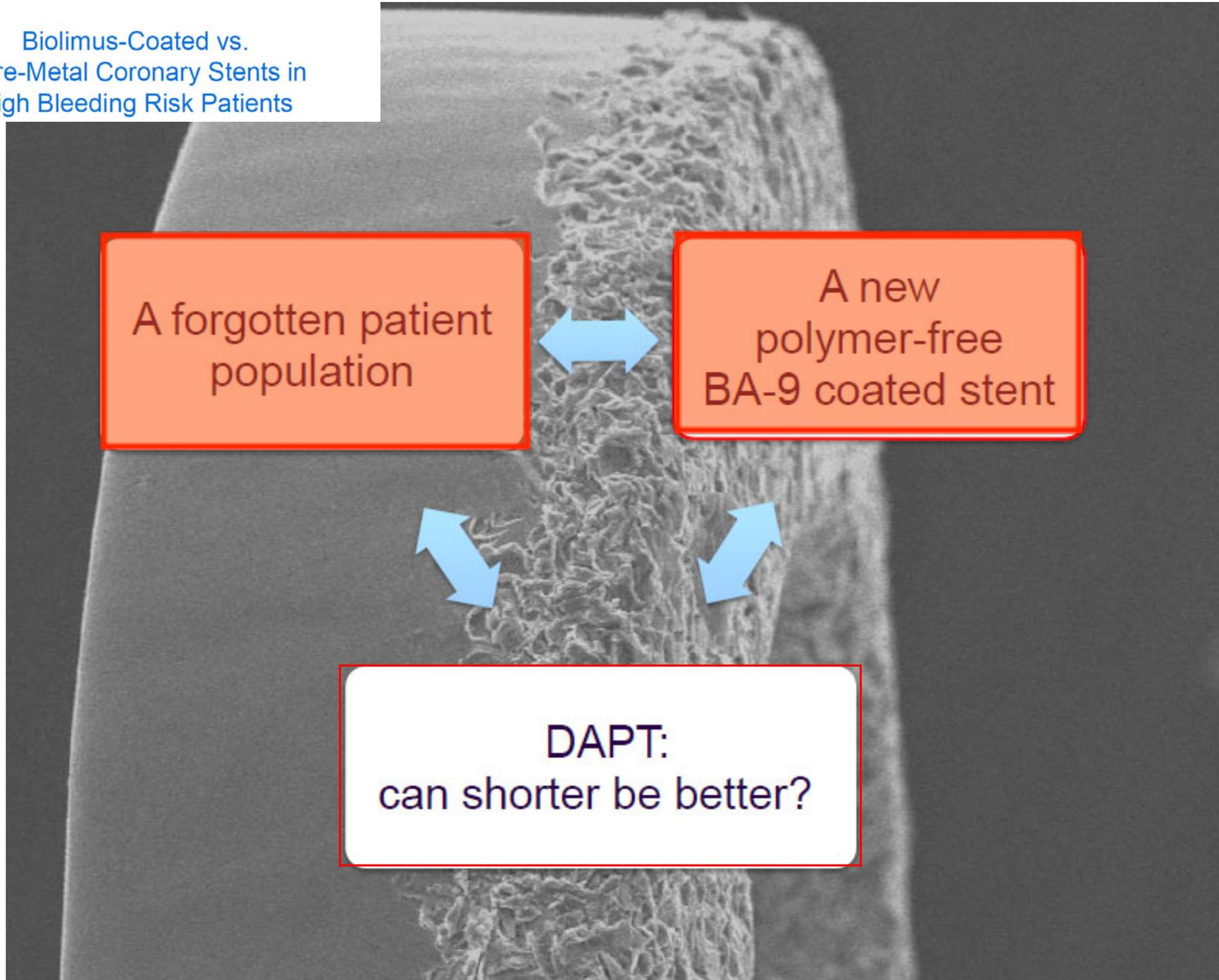
Assenza di polimero

Elevata lipofilia del farmaco rilasciato



Rapida riendotelizzazione

Biolimus-Coated vs.
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High Bleeding Risk Patients



A forgotten patient population

A new polymer-free BA-9 coated stent

DAPT:
can shorter be better?

LEADERS FREE Trial Design

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

**BioFreedom™
DCS**

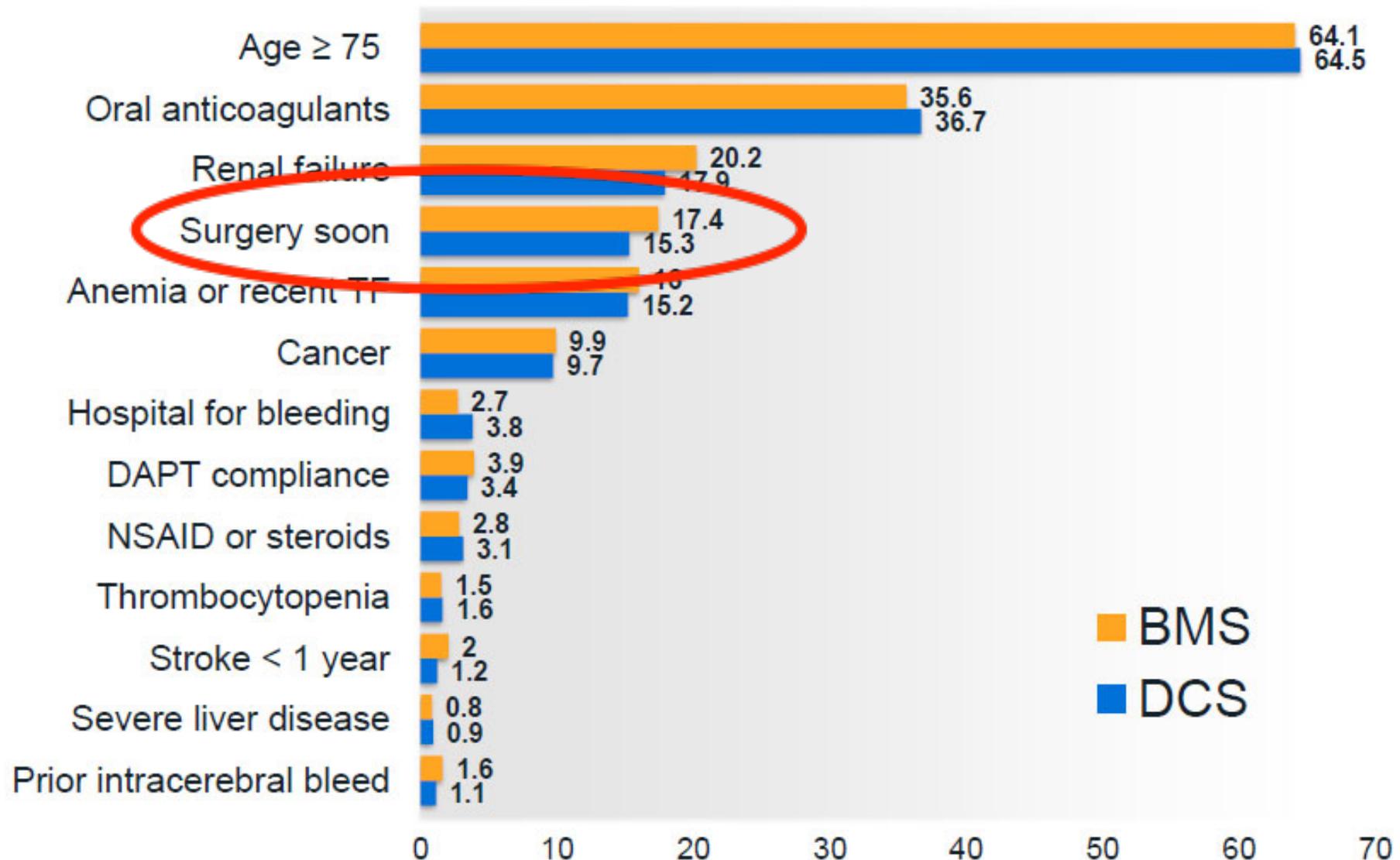
VS.

**Gazelle™
BMS**

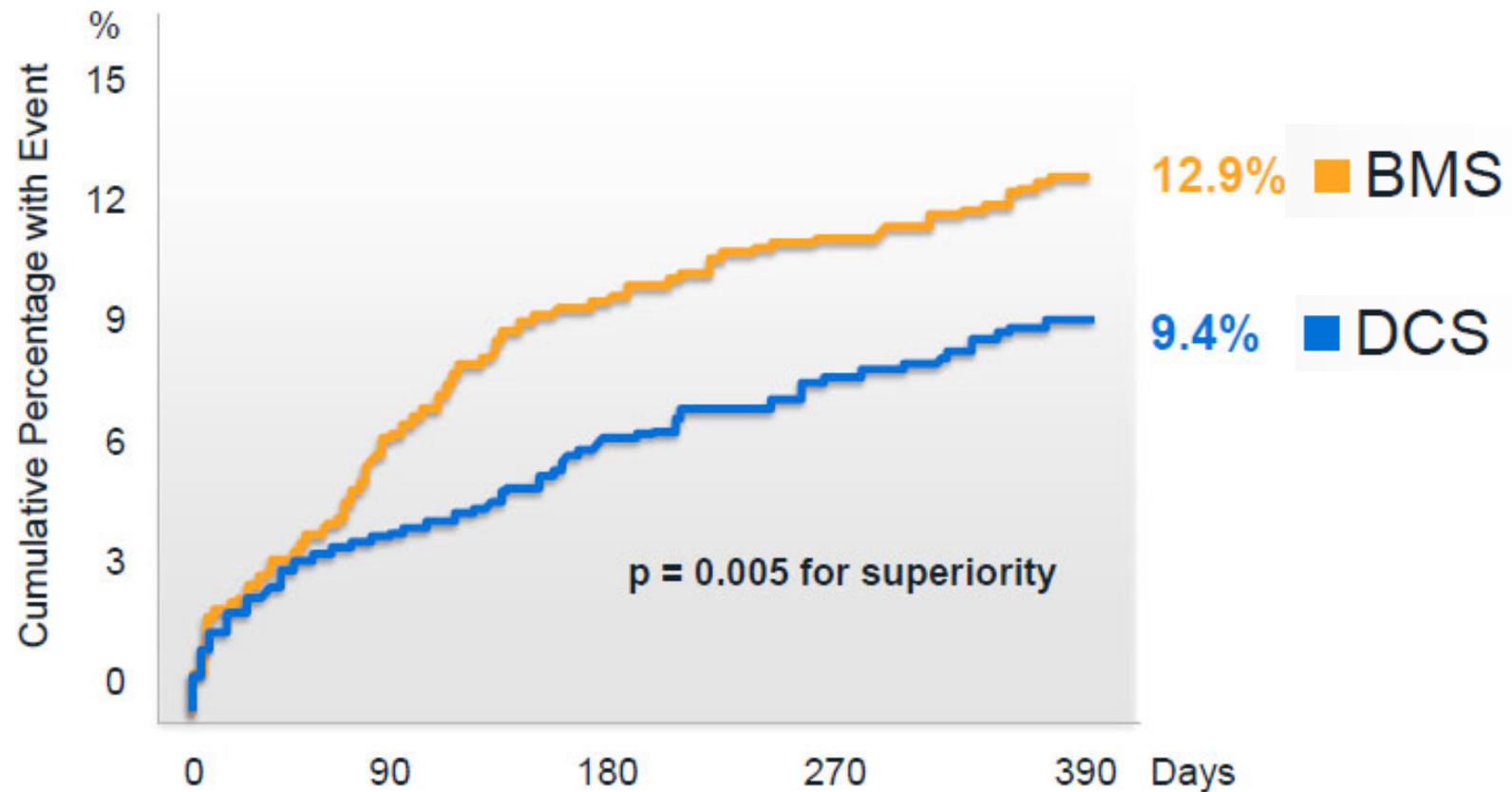
DAPT mandated for 1 month only, followed by long-term SAPT

- **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)

Inclusion Criteria Applied (1.7 criteria / patient)



Primary Safety Endpoint (Cardiac Death, MI, ST)



Risk difference:

- -3.6% (95% CI -6.1% to -1.0%)
- HR 0.71, (95% CI = 0.56 – 0.91)
- $p < 0.0001$ for non-inferiority
- $p = 0.005$ for superiority

ORIGINAL ARTICLE

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

N ENGL J MED 373;21 NEJM.ORG NOVEMBER 19, 2015

- ✓ LEADERS FREE is the first randomized clinical trial dedicated to HBR patients
- ✓ Such patients are often excluded from stent and drug trials, constitute a rapidly growing proportion of PCI candidates and suffer high event rates
- ✓ Together with a one-month only DAPT course, the use of a BA9-DCS was both significantly safer and more effective than a control BMS in HBR patients

Conclusioni

EDITORIAL COMMENT

**Tailored therapy :
strategia tagliata su
misura**

**Stent Selection and
Antiplatelet Therapy Duration
One Size Does Not Fit All***

David E. Kandzari, MD

VOL. 65, NO. 8, 2015

ISSN 0735-1097/\$36.00

<http://dx.doi.org/10.1016/j.jacc.2014.11.055>

**La valutazione del rischio beneficio del singolo paziente
in termini di rischio emorragico/trombotico deve
spingersi fino al laboratorio di emodinamica piuttosto
che una strategia “uguale per tutti”**

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Conclusioni

In pazienti ad elevato rischio di sanguinamento o in attesa di interventi chirurgici non cardiaci abbiamo ora delle alternative sicure ed efficaci per ridurre la durata della terapia antiaggregante dopo rivascolarizzazione percutanea

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Grazie

