Gestione perioperatoria dei pazienti in terapia antitrombotica

Stent & Chirurgia

Torino
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Disclosure

Speaker fee: Aspen, Astra Zeneca, Bayer, BMS, Boehringer, Eli Lilly, Daichii Sankio, Bayer, Pfizer, Sanofi

Advisory board member: Eli Lilly,Daiichi Sankyo, BMS, Pfizer, Sanofi, Bayer

Overview

La sospensione precoce della DAPT

La chirurgia non cardiaca nel paziente sottoposto a PCI

Linee guida e documenti di consenso

Cosa c'e' di nuovo

Come comportarsi concretamente

Optimal duration of dual antiplatelet therapy

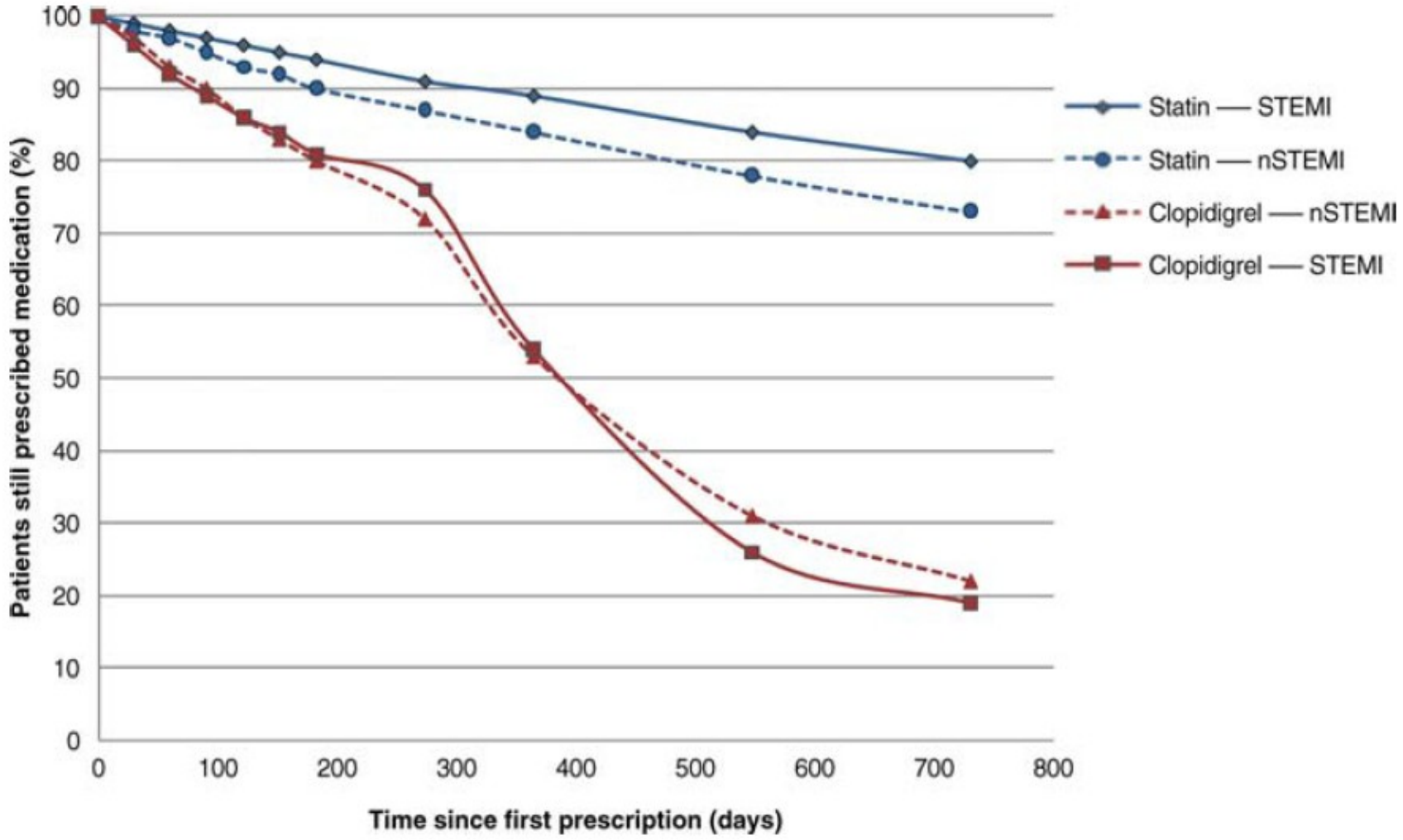
Stent thrombosis after coronary stent implantation is a serious condition associated with poor clinical outcomes

Treatment of patients with dual antiplatelet therapy for at least 4 weeks after bare-metal stent implantation has reduced the incidence of stent thrombosi to < 1%

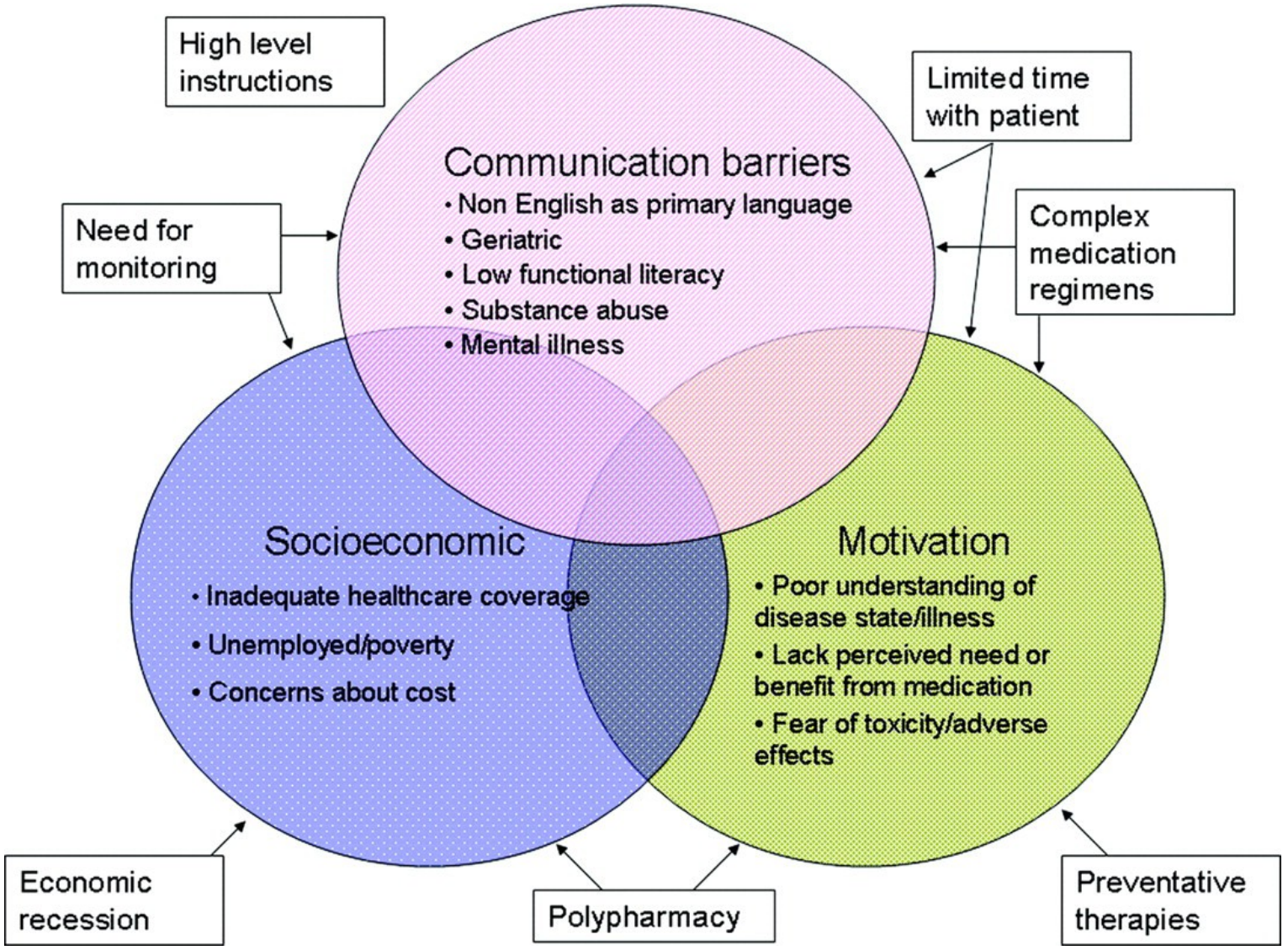
The optimal duration of dual antiplatelet therapy after implantation of a DES still remain unknown (risk of late-30gg-1 yy- and very late thrombosis ->12 m-)

Current guidelines recommend 6 to 12 months of dual antiplatelet therapy after DES

Discontinuation of clopidogrel and statin prescribing in primary care following non-ST-elevation myocardial infarction or ST-elevation myocardial infarction



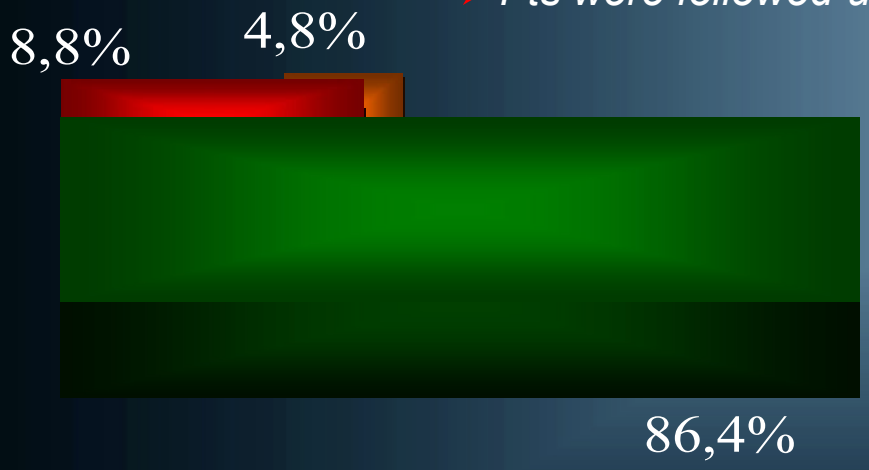
Causes of medication nonadherence



Prevalence, Predictors, and Long-Term Prognosis of Premature Discontinuation of Oral Antiplatelet Therapy After Drug Eluting Stent Implantation

Roberta Rossini, MD, PhD[a,*], Davide Capodanno, MD[b], Corrado Lettieri, MD[c], Giuseppe Musumeci, MD[a], Tamar Nijaradze, MD[a], Michele Romano, MD[c], Nikoloz Lortkipanidze, MD[a], Nicola Cicorella, MD[c], Giuseppe Biondi Zoccai, MD[d], Vasile Sirbu, MD[a], Antonio Izzo, MD[c], Giulio Guagliumi, MD[a], Orazio Valsecchi, MD[a], Antonello Gavazzi, MD[a], and Dominick J. Angiolillo, MD, PhD[b]

- *1358 consecutive pts treated with DES discharged on ASA (100 mg/day) + clopidogrel (75 mg/day)*
- *Clopidogrel was to be maintained for 12 months*
- *Pts were followed-up for 32.4±11.3 months*



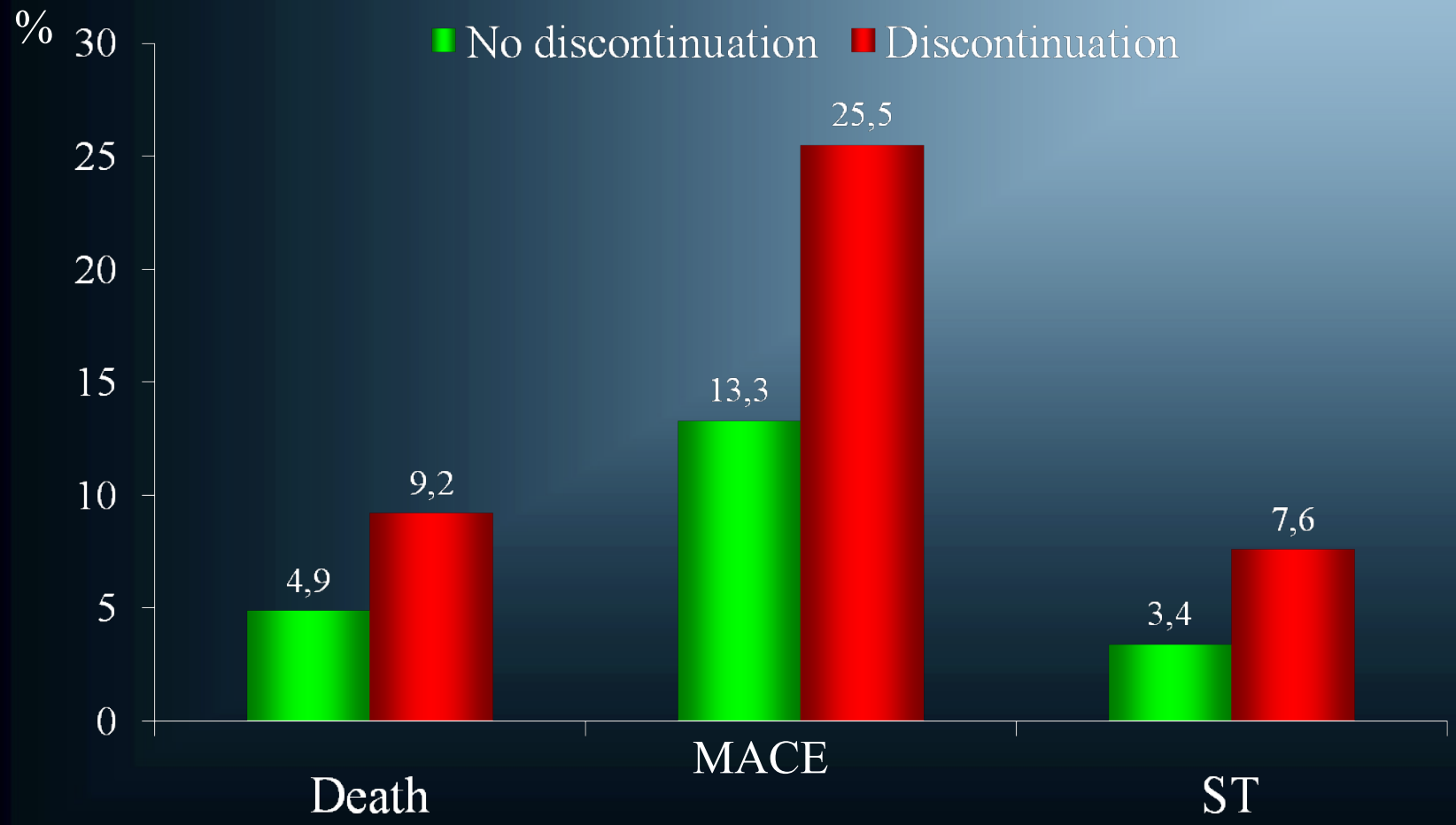
Discontinuation Causes:

- Surgery 34.5%
- Bleeding 21%
- Medical decision 17.6%
- Dental interventions 7.6%
- Economic/burocratic reasons 5.9%
- Anticoagulant therapy 5.0%

Rossini R et al. Am J Card 2011, 107: 186-194

Discontinuation and Prognosis

Pts who discontinued antiplatelet therapy had a higher incidence of death, MACE and stent thrombosis



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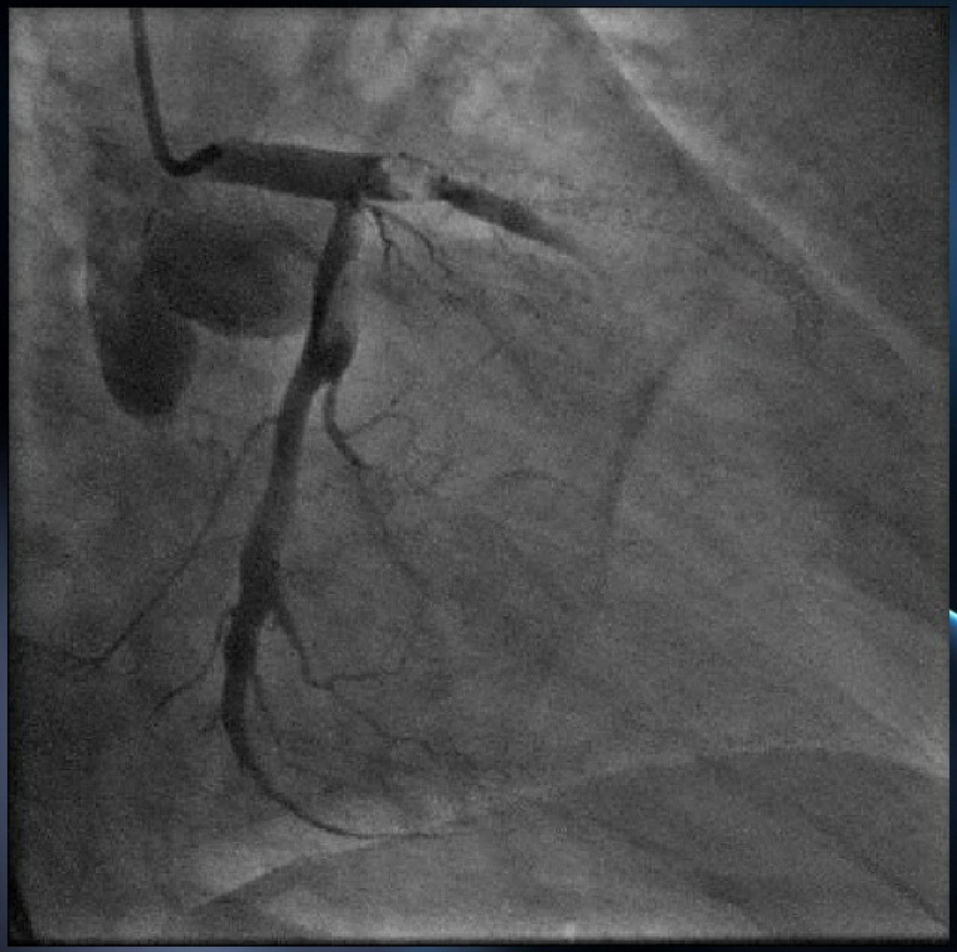
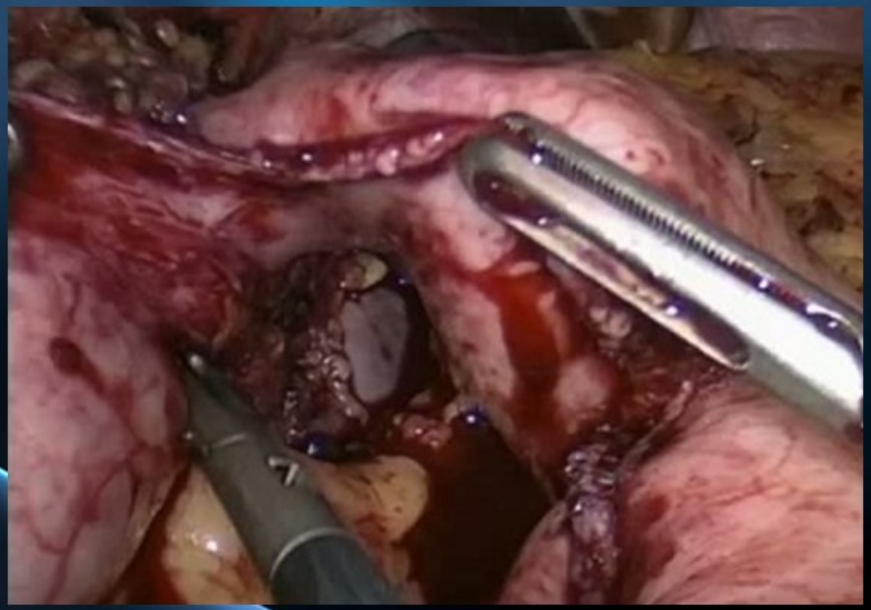
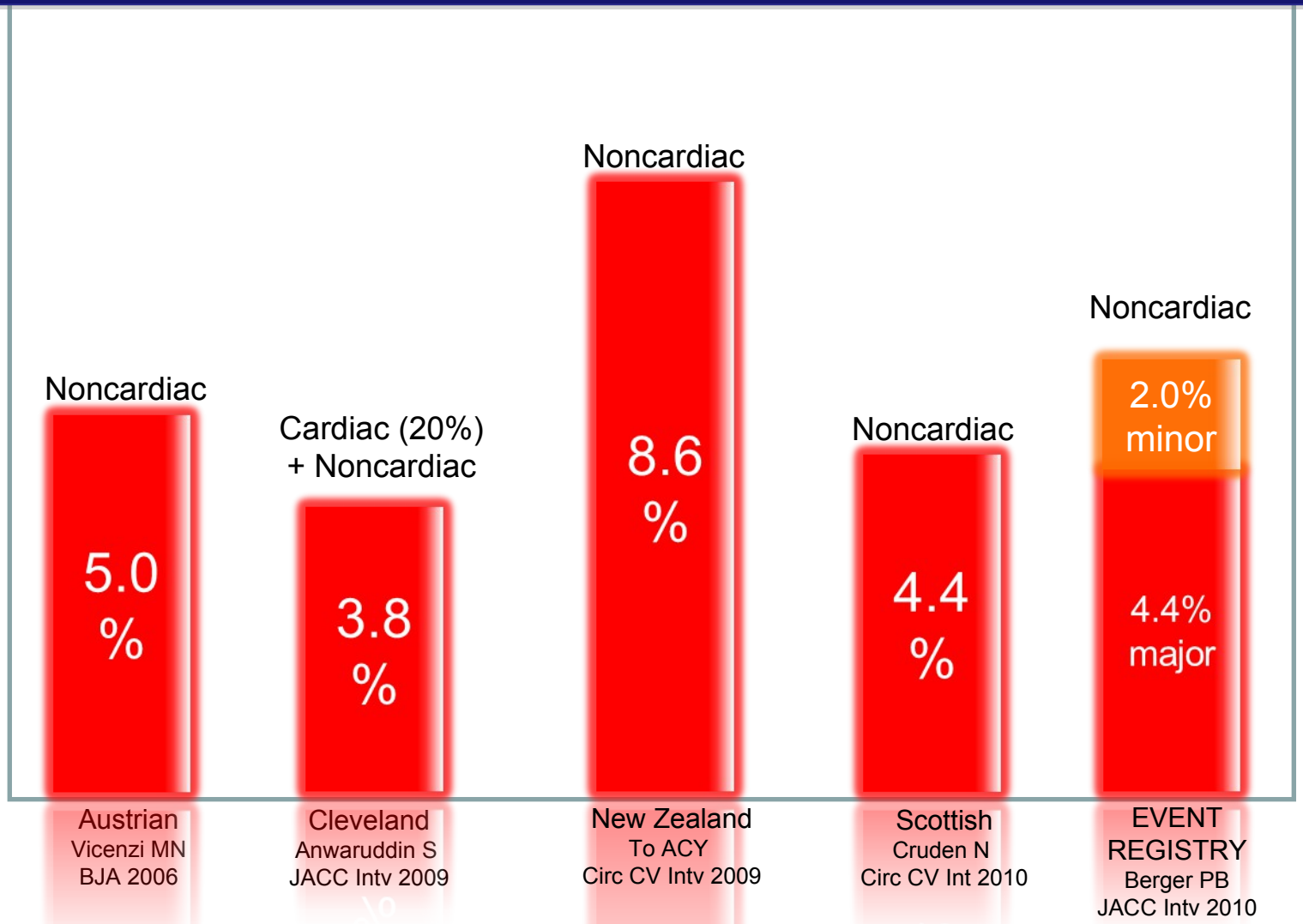
The problem





Incidence of surgery within 1 year after coronary stenting



S.Savonitto et al. Journal of Thrombosis and Haemostasis, 2011; 9: 2133–2142

Independent predictors of cardiac and bleeding events within hospitalization for surgery

Retrospective study: 670 pts OORR Bergamo, Mantova, Grosseto

OUTCOME	OR	95% LCL	95% UCL	P value
MACCE*				
LVEF at surgery admission (per % of increase)	0.9	0.9	0.99	0.02
Drop in haemoglobin (per mg/dL of decrease)	1.1	1.1	1.2	<0.001
Insulin-dependent diabetes mellitus	3.7	1.02	13.6	0.047
On dual antiplatelet therapy at the time of surgical indication	2.5	1.04	5.8	0.04
Aspirin discontinuation	4.8	1.2	19.5	0.03
Discontinuation of aspirin and/or thienopyridines >5 days before surgery	3.3	1.1	10	0.03

OUTCOME	OR	95% LCL	95% UCL	P value
TIMI major bleeding**				
On VKA at the time of surgery	2.4	1.2	5.0	0.02
On dual antiplatelet therapy at the time of surgrical indication	2.4	1.4	3.7	0.001
TIMI minor bleeding***				
Bridging with LMWH	2.1	1.2	3.6	0.006

Rossini R et al. ESC 2012

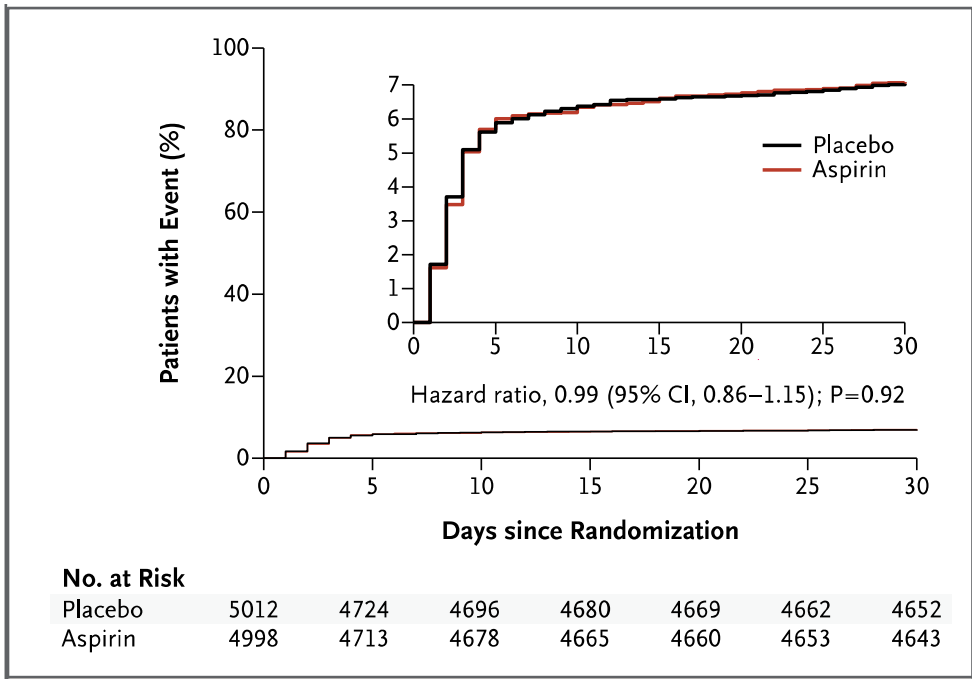
Cardiovascular risks after low-dose aspirin perioperative withdrawal versus bleeding risks with its continuation

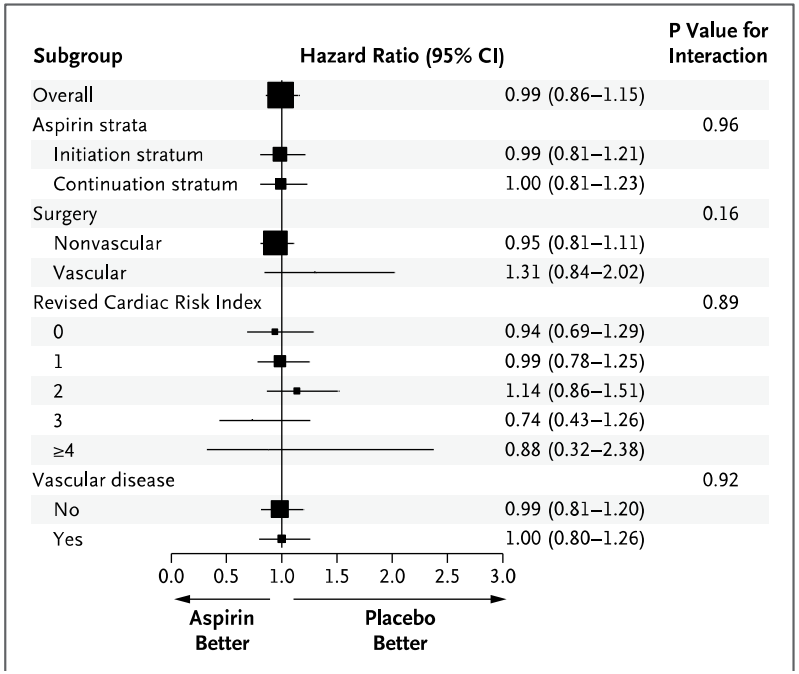
Meta-analysis of 41 studies (12 observational retrospective, 19 observational prospective, 10 randomized), including 49 590 patients (14 981 on aspirin, 34 609 controls).

Aspirin multiplied baseline bleeding rate by a factor of 1.5 (median, interquartile range: 1.0–2.5). Mortalities, possibly caused by bleeding, occurred only after transurethral prostatectomy

W. Burger, et al. Journal of Internal Medicine 2005; 257: 399–414

Aspirin in Patients undergoing non cardiac surgery: the POISE-2 trial





Randomized, prospective trial, including 10010 patients at risk for vascular complications, undergoing non cardiac surgery. Primary outcome: composite of death or non fatal MI at 30 dd

Devereaux PJ et al. New Engl J Med 2014: 370: 1494

Previous Coronary Stent Implantation and Cardiac Events in Patients Undergoing Noncardiac Surgery

Table 1. Frequency of Noncardiac Surgical Procedures Performed in Patients Treated With Previous Coronary Stenting

Surgical Group	n	%
Vascular	201	10
Endocrine	73	4
Nose, throat, and respiratory	90	5
Digestive system	316	16
Neurological	118	6
Cosmetic and reconstructive	363	19
Orthopedic and spinal	652	33
Ophthalmic, aural, and maxillofacial	19	1
Genitourinary and reproductive	121	6
Total	1953	100

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LG ESC 2014 Chirurgia non cardiaca

Recommendations	Class[a]	Level[b]
It is recommended that aspirin be continued for 4 weeks after BMS implantation and for 3–12 months after DES implantation, unless the risk of life-threatening surgical bleeding on aspirin is unacceptably high.	I	C
Continuation of aspirin, in patients previously thus treated, may be considered in the peri-operative period, and should be based on an individual decision that depends on the peri-operative bleeding risk, weighed against the risk of thrombotic complications.	IIb	B
Discontinuation of aspirin therapy, in patients previously treated with it, should be considered in those in whom haemostasis is anticipated to be difficult to control during surgery.	IIa	B

Recommendations	Class[a]	Level[b]
Continuation of $P2Y_{12}$ inhibitor treatment should be considered for 4 weeks after BMS implantation and for 3–12 months after DES implantation, unless the risk of life-threatening surgical bleeding on this agent is unacceptably high.	IIa	C
In patients treated with $P2Y_{12}$ inhibitors, who need to undergo surgery, postponing surgery for at least 5 days after cessation of ticagrelor and clopidogrel—and for 7 days in the case of prasugrel—if clinically feasible, should be considered unless the patient is at high risk of an ischaemic event.	IIa	C

Eur Heart J. 2014;35:2383-431

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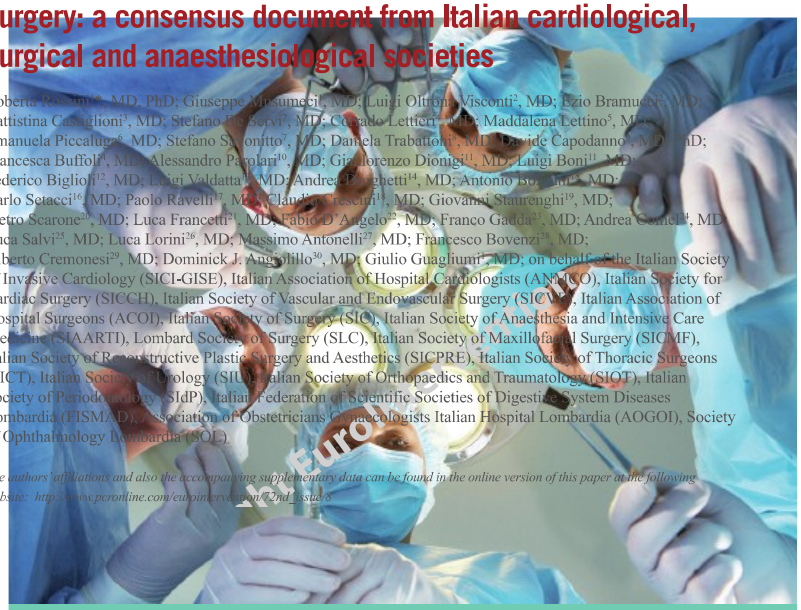
EuroIntervention 2014;10:38-46

FOCUS ARTICLE

Un'iniziativa congiu

Perioperative management of antiplatelet therapy in patients with coronary stents undergoing cardiac and non-cardiac surgery: a consensus document from Italian cardiological, surgical and anaesthesiological societies



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The authors' affiliations and also the accompanying supplementary data can be found in the online version of this paper at the following website: http://www.pcronline.com/eurointervention/72nd_issue/8

Stent coronarico e chirurgia: la gestione perioperatoria della terapia antiaggregante nel paziente portatore di stent coronarico candidato a intervento chirurgico

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*Federazione Italiana delle Società Scientifiche delle Malattie dell'Apparato Digerente***
(Marco Soncini, Giancarlo Spinzi, Maurizio Vecchi)
*Società Italiana Chirurgia Maxillo-Facciale**
(Giuseppe Ferronato, Chirurgia Maxillo-Facciale, Azienda Ospedaliero Universitaria di Padova)
*Società Italiana di Chirurgia Cardiaca**
(Piersilvio Gerometta, U.O. di Cardiochirurgia, Humanitas Gavazzeni, Bergamo)

*endorsement nazionale, **endorsement regionale.
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Gli autori dichiarano nessun conflitto di interessi.
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DEFINIZIONE DEL RISCHIO TROMBOTICO

RISCHIO BASSO	RISCHIO INTERMEDIO	RISCHIO ALTO
• > 6 mesi dopo PCI con BMS	• >1 mese < 6 mesi dopo PCI con BMS;	• <1 mese dopo PCI con BMS
	• > 6 <12 mesi dopo DES;	• <6 mesi dopo DES
• >12 mesi dopo PCI con DES.	• >12 mesi dopo DES a rischio elevato (stent lunghi, multipli, in overlapping, piccoli vasi, biforcazioni, tronco comune, last remaining vessel).	• <12 mesi dopo DES a rischio elevato (stent lunghi, multipli, in overlapping, piccoli vasi, biforcazioni, tronco comune, last remaining vessel).

La presenza di ACS in occasione della PCI, EF <35%, IRC, DM aumentano il rischio di trombosi intrastent.

I pazienti sottoposti a CABG ed i pazienti con sindrome coronarica acuta non sottoposti a PCI vengono considerati ad alto rischio entro il 1°mese, rischio intermedio tra 1 e 6 mesi, basso rischio oltre i 6 mesi.

I pazienti sottoposti a POBA sono ritenuti ad alto rischio entro 2 settimane, a rischio intermedio tra 2 e 4 settimane, a basso rischio oltre le 4 settimane.

Terapia antitrombotica e chirurgia generale

Table 3. General surgery.

			Thrombotic risk		
			Low risk	Intermediate risk	High risk
Haemorrhagic risk	Low risk	Hernioplasty, plastic surgery of incisional hernias, cholecystectomy, appendectomy and colectomy, gastric resection, intestinal resection, breast surgery	ASA: continue $P2Y_{12}$ receptor inhibitors: - Discontinue 5 days before [a] - Resume within 24-72 hours, with a loading dose	Elective surgery: postpone Non-deferrable surgery: ASA: continue $P2Y_{12}$ receptor inhibitors: continue	Elective surgery: postpone Non-deferrable surgery: ASA: continue $P2Y_{12}$ receptor inhibitors: continue
	Intermediate risk	Haemorrhoidectomy, splenectomy, gastrectomy, obesity surgery, rectal resection, thyroidectomy	ASA: continue $P2Y_{12}$ receptor inhibitors: - Discontinue 5 days before [a] - Resume within 24-72 hours, with a loading dose	Elective surgery: postpone Non-deferrable surgery: ASA: continue $P2Y_{12}$ receptor inhibitors: - Discontinue 5 days before [a] - Resume within 24-72 hours, with a loading dose [b]	Elective surgery: postpone Non-deferrable surgery: ASA: continue $P2Y_{12}$ receptor inhibitors: - Discontinue 5 days before [a] - Resume within 24-72 hours, with a loading dose Bridge therapy with GPIIb/IIIa inhibitors [b]
	High risk	Hepatic resection, duodenocefalopancreasectomy	ASA: Discontinue $P2Y_{12}$ receptor inhibitors: - Discontinue 5 days before [a] - Resume within 24-72 hours, with a loading dose	Elective surgery: postpone Non-deferrable surgery: ASA: continue $P2Y_{12}$ receptor inhibitors: - Discontinue 5 days before [a] - Resume within 24-72 hours, with a loading dose [b]	Elective surgery: postpone Non-deferrable surgery: ASA: continue $P2Y_{12}$ receptor inhibitors: - Discontinue 5 days before [a] - Resume within 24-72 hours, with a loading dose Bridge therapy with GPIIb/IIIa inhibitors [b]

[a] 7 days prior for prasugrel; [b] collegial discussion of risk, even with family/patient. References [66, 101]. ASA: aspirin

Rossini et al EuroIntervention. 2014;10:38-46.

Phase 2 protocol (Simon's two-stage design)

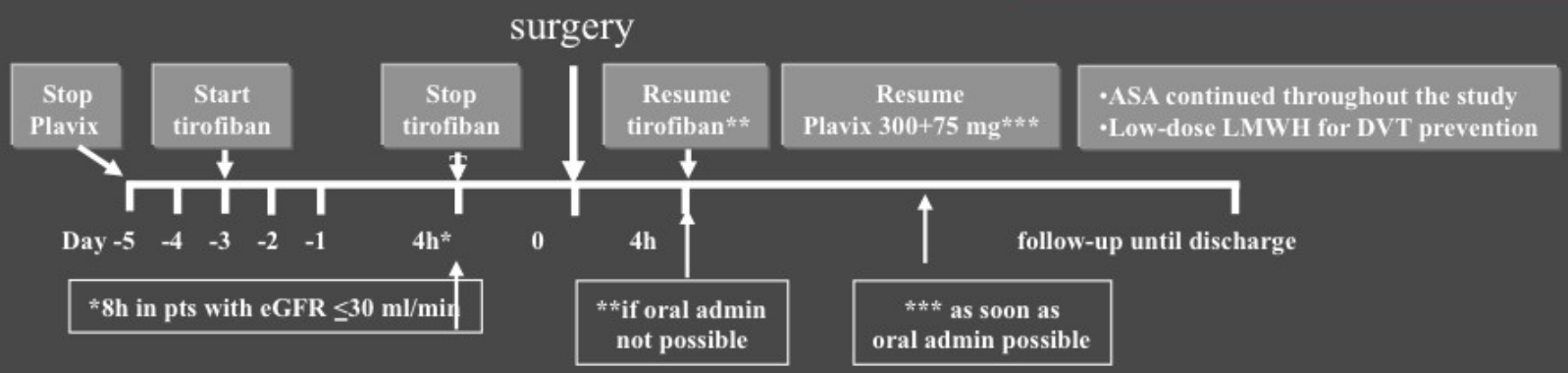
Inclusion criteria

Patients within 6-12 months of DES implantation
+
high-risk for surgical bleeding, "so that the surgeon would not operate on clopidogrel"

12 months in the case of high-risk of ST:
- stent implantation due to an ACS
- diabetes
- renal insufficiency
- severe LV dysfunction
- DES in LMCA, proximal LAD, bifurcation

Exclusion criteria

- Allergy to tirofiban
- Thrombocytopenia <100.000
- Stroke < 30 days or prior ICH
- Intracranial disease
- Uncontrolled hypertension
- Unable to sign consent form



Tirofiban: **0.4 mg/kg/min over 30', followed by 0.1 mg/kg/min**
Or 0.05 mg/kg/min if eGFR <30 ml/min

Primary EP: the composite of Death, MI, stent thrombosis, haemostatic reoperation
Secondary EP: TIMI major bleeding

Savonitto S, Br J Anaesth 2010; 204:285-91

Niguarda & Legnano experience

PATIENT ENROLLED	**60**		
Cardiac	**21**		
Urinary tract	**7**		
Gastrointestinal	**20**		
Mixed surgery	**12**		
PRIMARY ENDPOINT*	**0**	**97.5%**	**CI 6%**
BLEEDING EVENTS**	**18**		
major	**2**		
minor	**3**		
transfusion	**13**		
SEVERE TROMBOCITOPENIA#	**1**		

S Savonitto, M. Caracciolo, M. Cattaneo, S. De Servi. J Thromb Haemost 2011;9: 2133–2142

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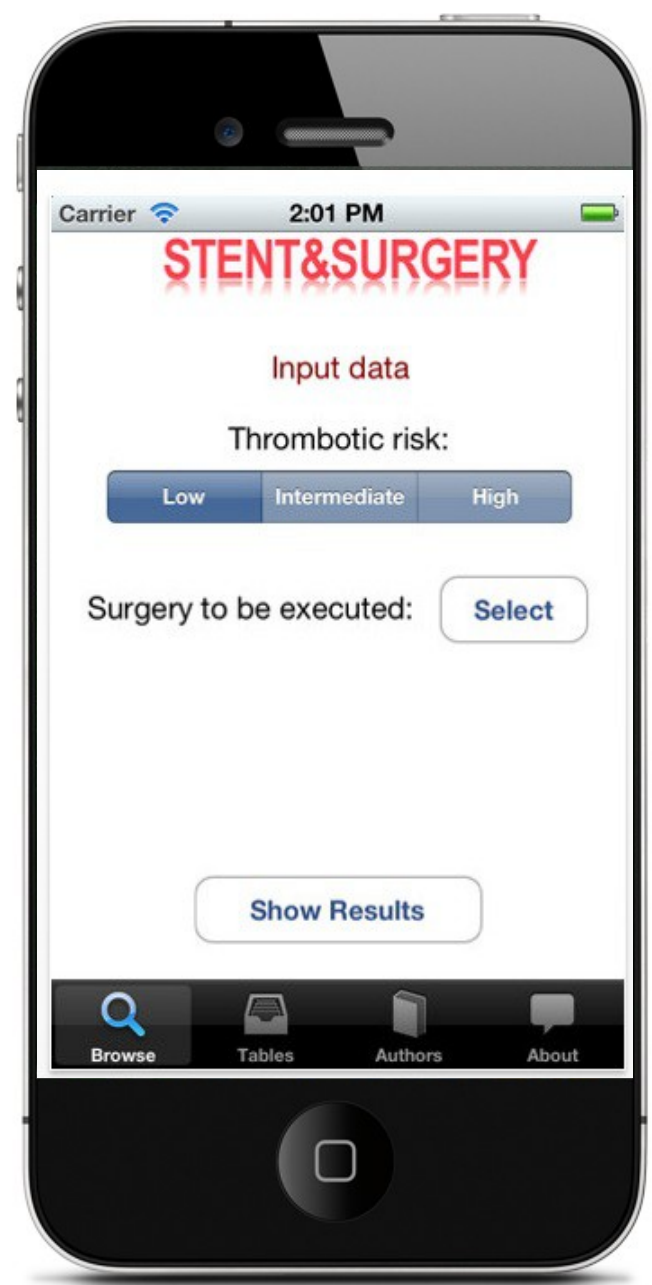
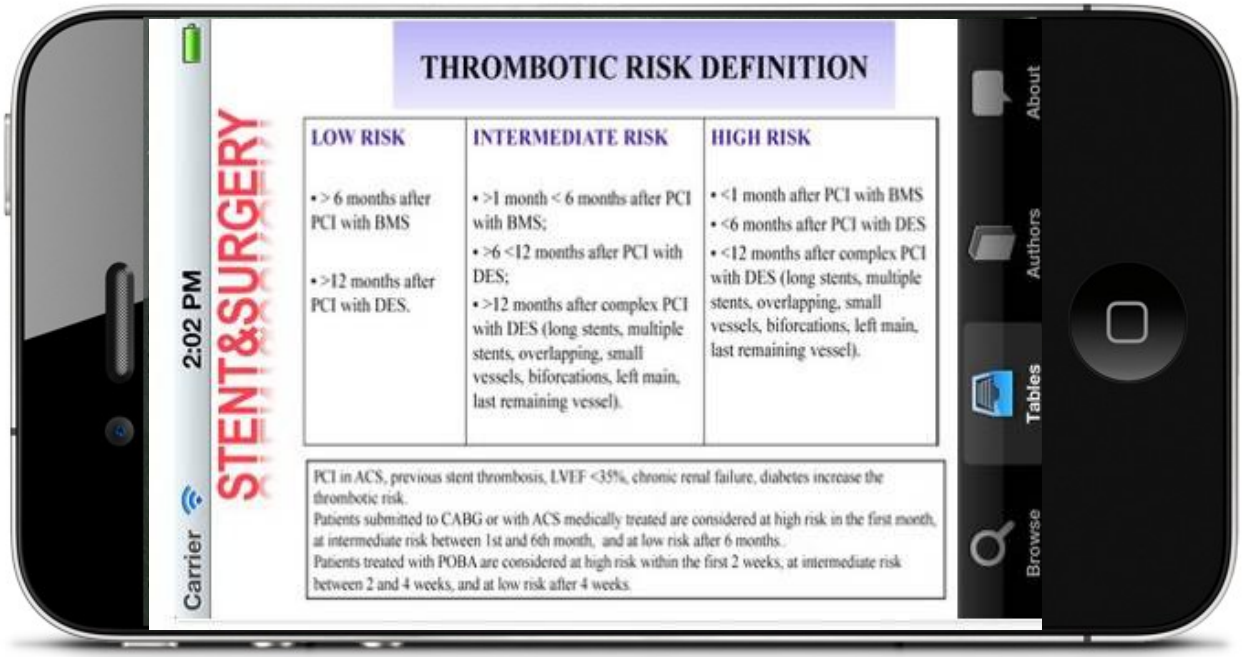
DOCUMENTO DI POSIZIONE: PUNTI CHIAVE

- Mantenere ASA nella maggior parte degli interventi
- Differire, quando possibile, interventi a rischio emorragico intermedio/alto
- Possibilità di sospensione del secondo antiaggregante dopo 6 mesi da PCI “non complicate”, se l’intervento ha un significativo rischio emorragico
- Wash-out di 5 giorni per Clopidogrel e Ticagrelor e 7 giorni per Prasugrel
- Praticare la terapia di “bridge” negli interventi ad elevato rischio ischemico ed emorragico



Coronary Stent & Surgery

Management of antiplatelet therapy in patient with coronary stent, who must be subjected to surgery



The SAS Registry

The Surgery After Stenting Registry (SAS):

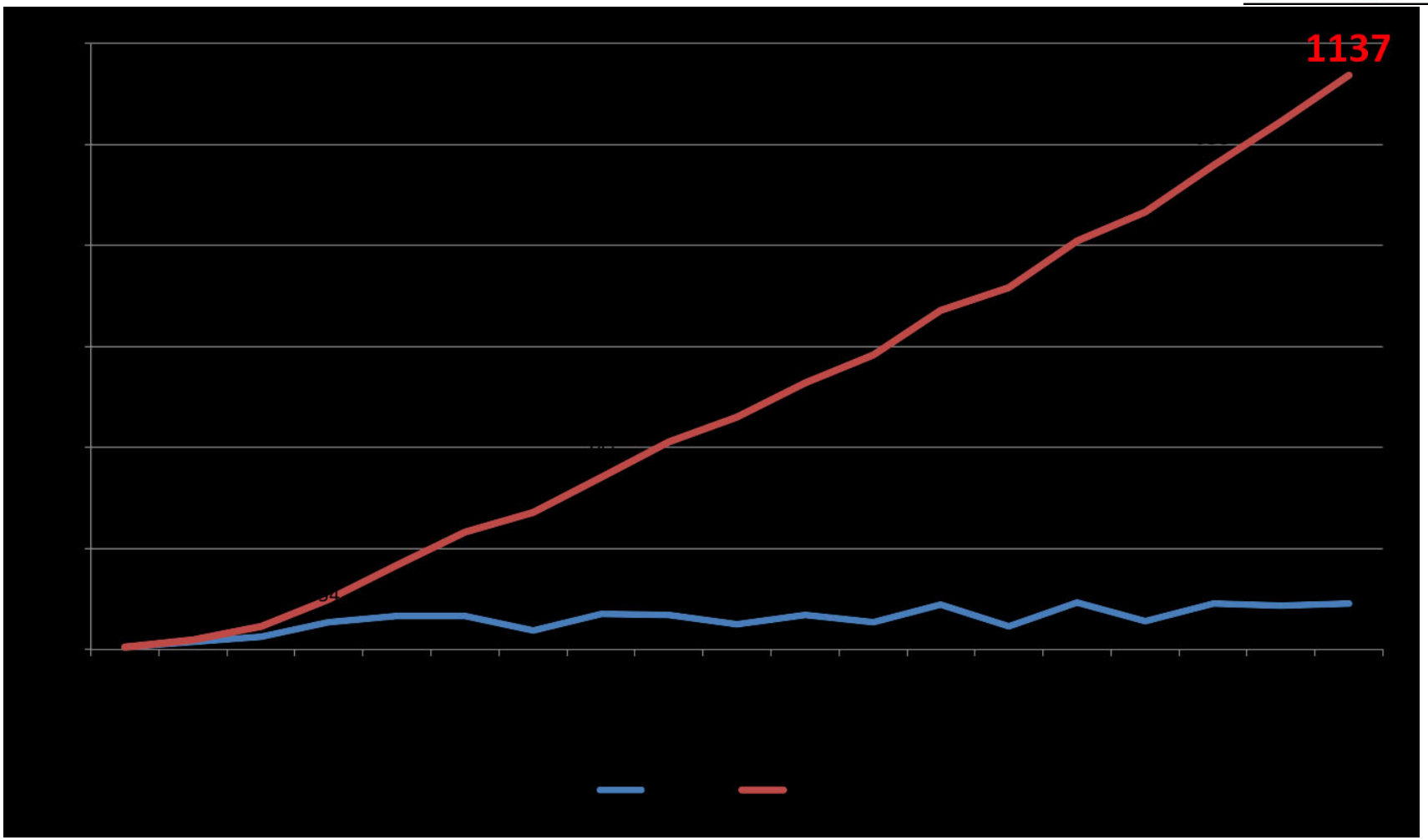
a multicentre registry of consecutive patients undergoing cardiac and non-cardiac surgery or operative endoscopic/endovascular procedures after implantation of a coronary stent

Co-Principal Investigators Roberta Rossini and Stefano Savonitto
On behalf of SAS Investigators and Italian Society of Invasive Cardiology (GISE)

Study End-points

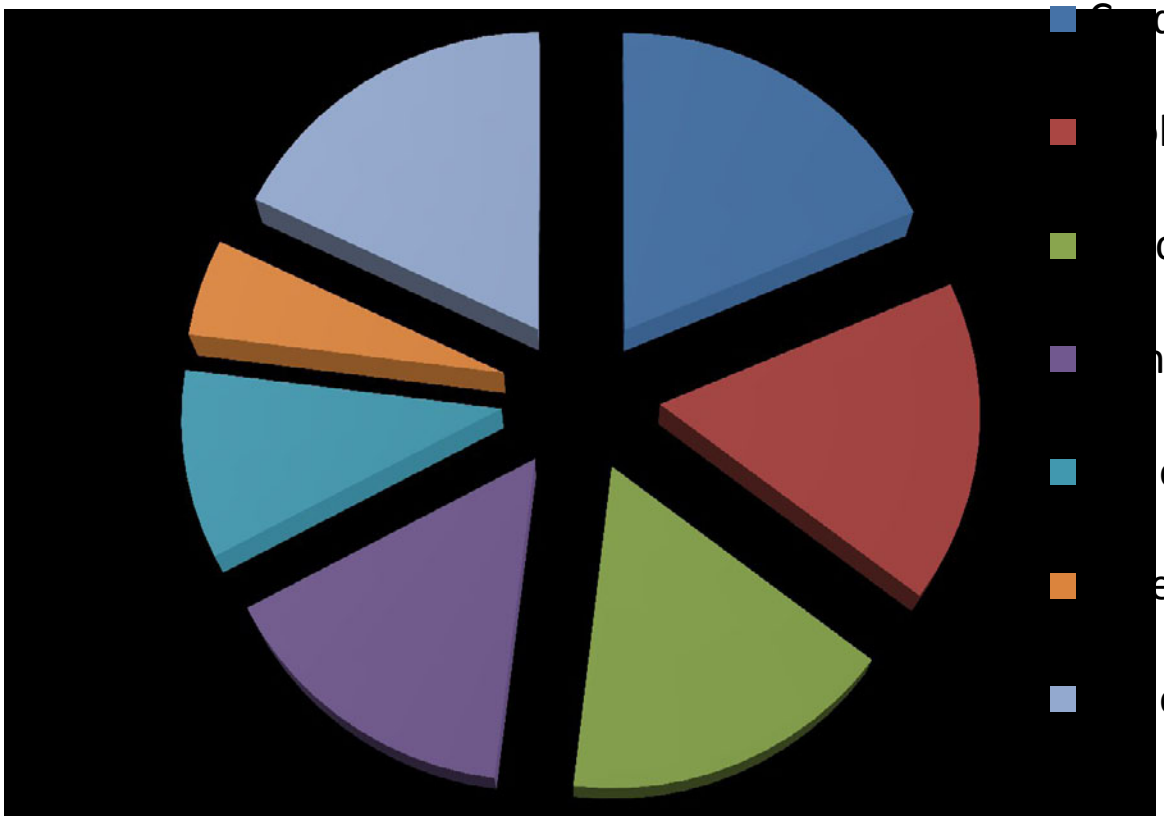
- **Primary end-points:**
  - Net adverse clinical events (NET): composite of death, myocardial infarction (MI), probable/definite stent thrombosis and Bleeding Academic Research Consortium (BARC) grade ≥3 bleeding during the index surgical admission
- **Secondary Endpoints:**
  - Composite of death, myocardial infarction and probable/definite stent thrombosis within 30 days of index surgical admission/procedure
  - Bleeding Academic Research Consortium (BARC) grade ≥3 bleeding within 30 days of index surgical admission/procedure

SAS enrolment curve



55 patients did not undergo any surgical procedure after providing consent: a total of **1082 patients were available for analysis**. There were no lost to follow-up at 30 days.

Details of surgical procedures



diac surgery n 202 (18.6%)

logy n. 182 (16,8%)

cular surgery n. 178 (16.5%)

neral surgery n. 165 (15.3%)

opedics n. 106 (9.8%)

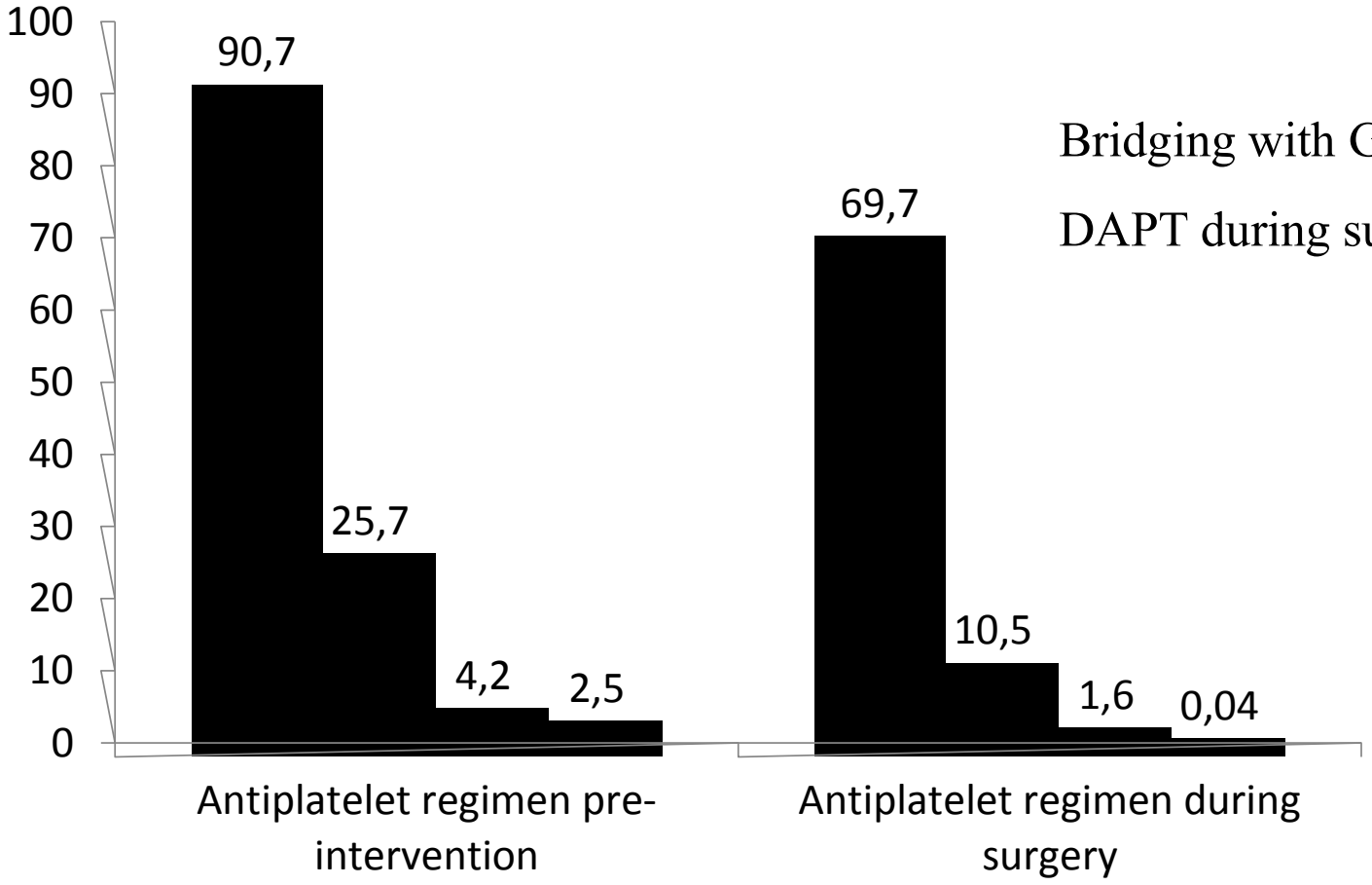
estive endoscopy n. 55 (5.1%)

er n. 194 (17.9%)

- Surgery <180 days from PCI, n. 116 (14.1%)
- Intermediate to high surgical bleeding risk, n. 558 (51.6%)

The SASRegistry

Details of Antithrombotic Therapy at the Time of Surgery or Invasive Procedure



Bridging with GPI 4.9%

DAPT during surgery 10.5%

Aspirin

Clopidogrel

Ticagrelor

Prasugrel

Stopped ASA pre interv. 23,1%

Length of discontinuation 11± 9 days

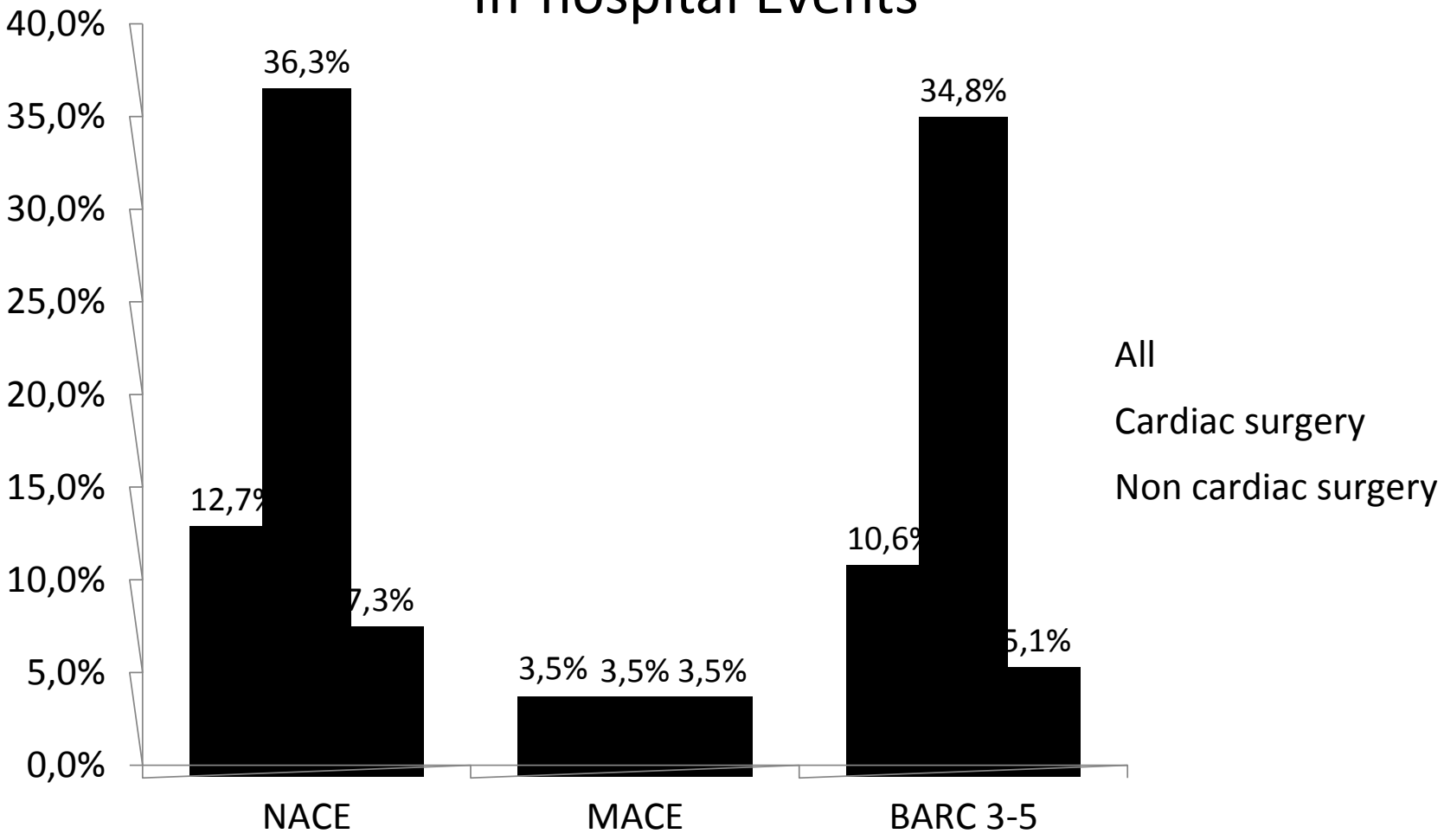
Stopped P2Y12 pre interv. 63.5%

Length of discontinuation 10± 7 days

Primary endpoint

Outcome Events after Surgery or Invasive Procedure

In-hospital Events



euro PCR 2015

Independent predictors of in-hospital NACE

Variable	Univariate OR (95%CI); P value	Multivariate OR (95%CI); P value	Multivariate (Cardiac surgery)	Multivariate (Noncardiac surgery)
BMI	1.00 (1.00-1.02); 0.18	-	-	-
Prior cerebrovascular accident	**1.50 (0.90-2.50); 0.12**	**2.56 (1.27-5.17); <0.01**	-	4.15 (1.90-9.07); <0.01
Malignancies	0.73 (0.47-1.14); 0.17	-	-	-
Acute coronary syndromes	0.41 (0.28-0.60); <0.01	-	0.37 (0.16-0.89); 0.03	-
DES	0.74 (0.51-1.09); 0.12	-	-	-
Second generation DES	0.83 (0.55-1.24); 0.35	-	-	-
Cardiac surgery	**7.27 (4.96-10.7); <0.01**	**4.76 (2.58-8.78); <0.01**	NA	NA
Surgery <180 days from PCI	**1.81 (1.08-3.04); 0.03**	**1.99 (1.02-3.90); 0.04**	-	4.61 (2.03-10.48); 0.01
Intermediate to high bleeding risk*	**5.29 (3.34-8.37); <0.01**	**3.24 (1.68-6.26); <0.01**	-	3.36 (1.69-6.70); <0.01
On P2 Y_{12} inhibitor pre intervention	0.72 (0.48-1.05); 0.09	0.36 (0.20-0.65); 0.01	0.35 (0.15-0.84); 0.02	0.36 (0.16-0.79); 0.01
Aspirin during surgery	2.80 (1.71-4.59); <0.01	-	-	-

In conclusione

- La percentuale di pazienti che necessitano di chirurgia dopo l'impianto di uno stent e' in continuo aumento
- Per ciascuno di essi e' necessario formulare una valutazione del rischio emorragico e di quello trombotico in modo tale da selezionare la strategia chirugica e il regime antitrombotico piu' adatto ad ogni singolo caso
- I pazienti valutati secondo quanto suggerito dal documento di consenso italiano hanno manifestato una modesta probabilita' di sanguinare e una bassissima incidenza di eventi avversi seri peri-operatori
- Le indicazioni terapeutiche sono in continua evoluzione cosi' come le tecniche chirurgiche volte a minimizzare i rischi e preservare i benefici