Perioperative Antiplatelet Therapy In Patients With Drug-Eluting Stent Undergoing Noncardiac SURgEry

ASSURE-DES Randomized Trial

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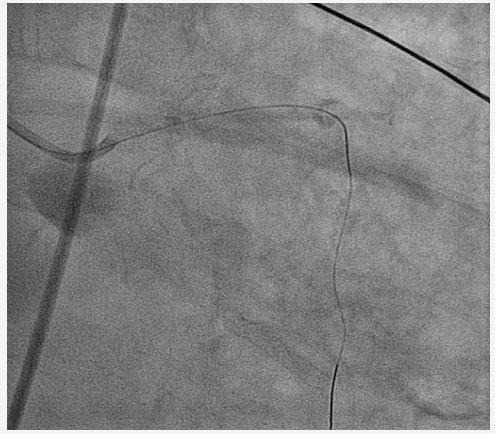
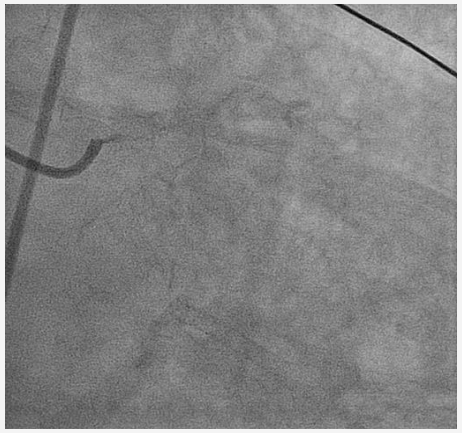
Disclosure

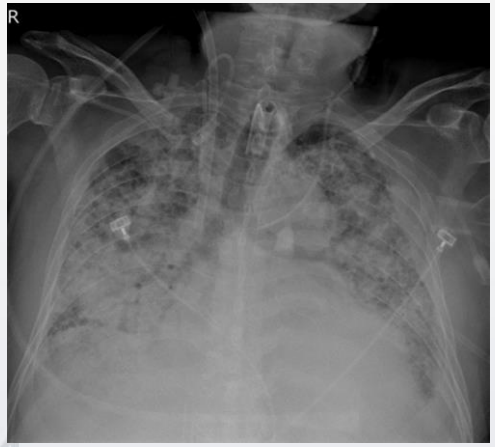
- I have nothing to disclosure

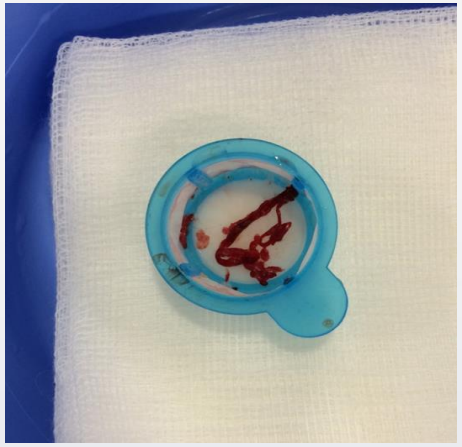
Perioperative Antiplatelet in patients with DES

Cessation







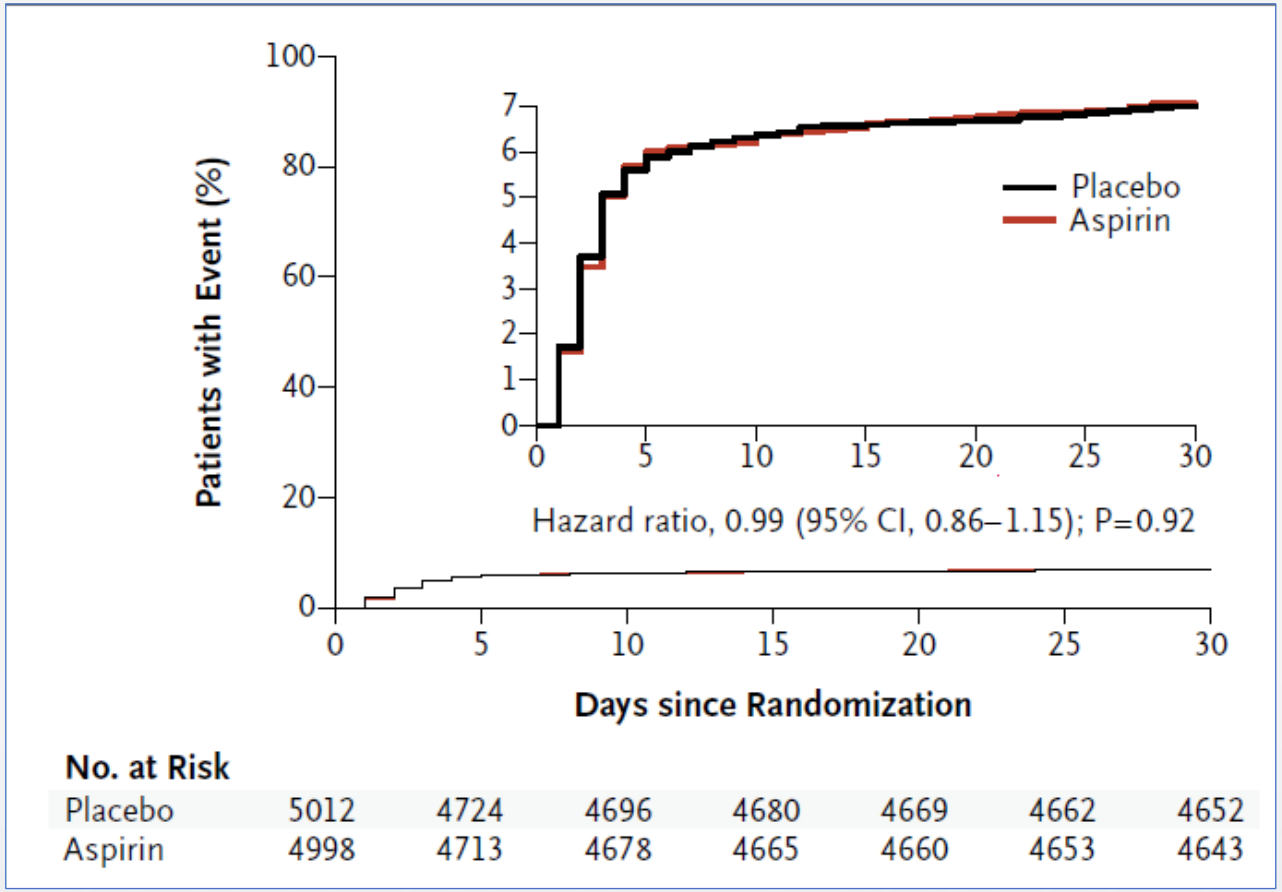


Continuation

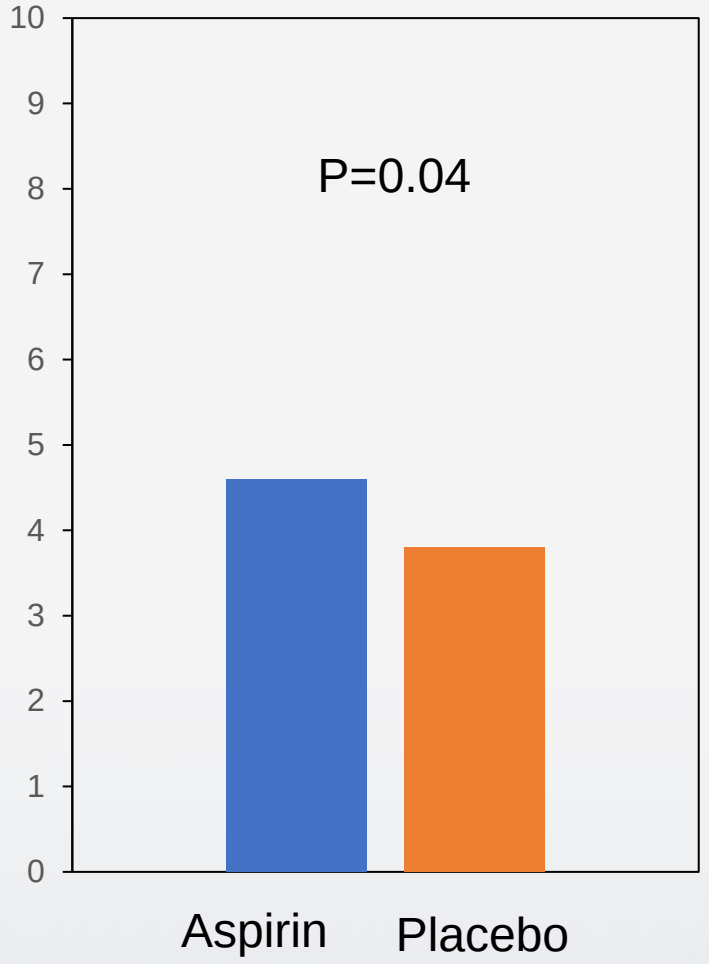
Bleeding

POISE-2: Aspirin in NCS

Death and Non Fatal MI



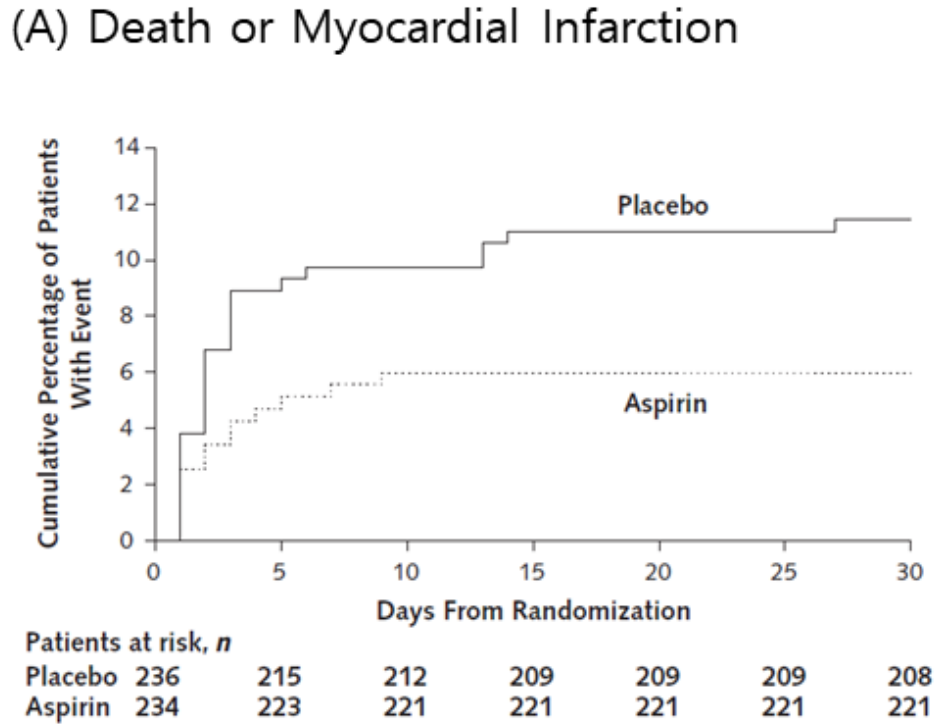
Major Bleeding

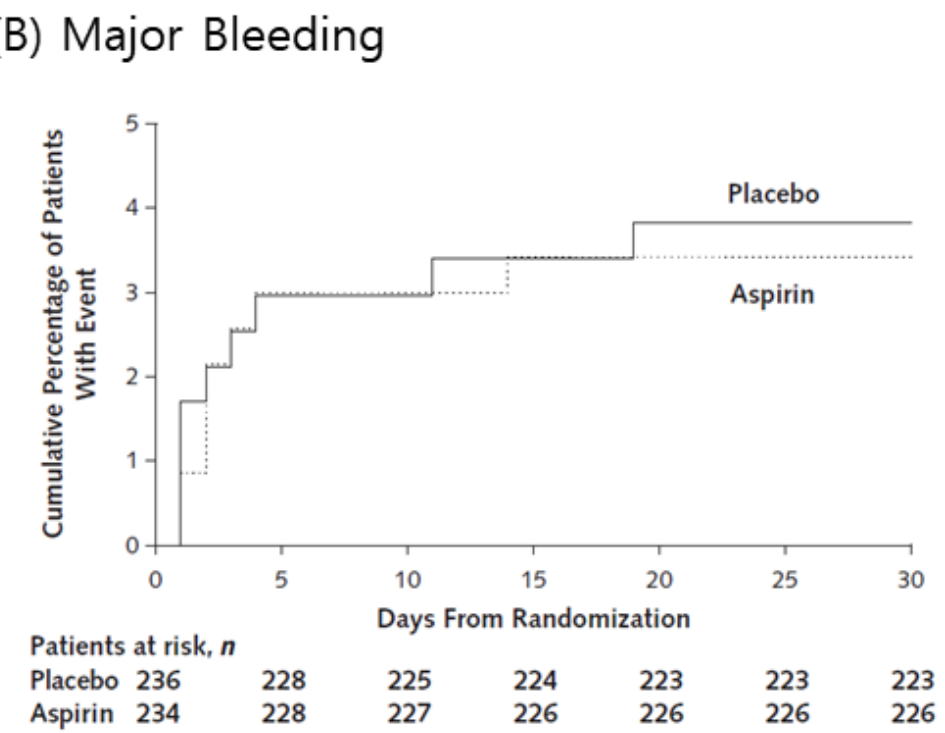


N Engl J Med 2014;370:1494-503.

Subgroup study: POISE-2

PCI patients





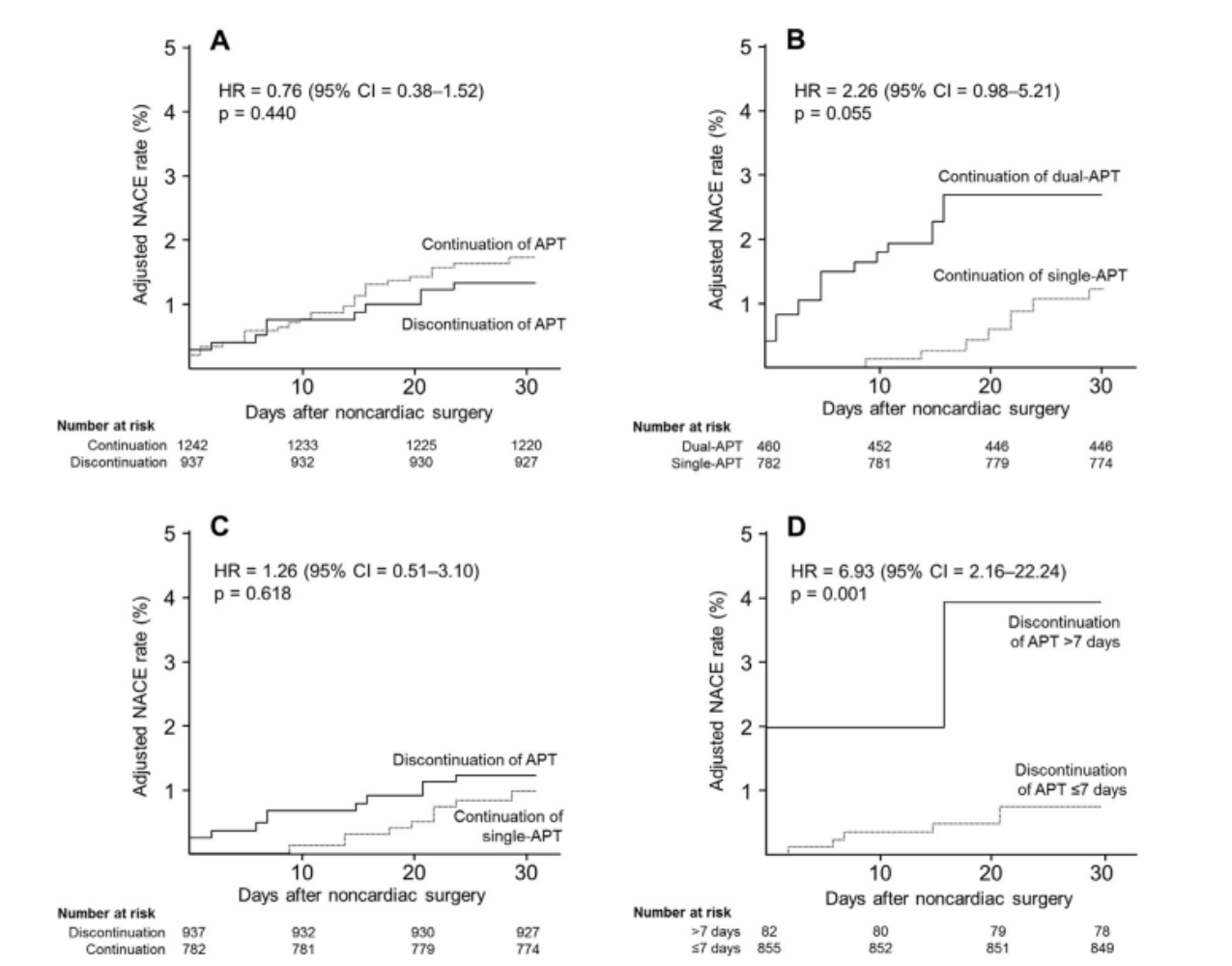
Death	0.9% vs. 1.3%
Non Fatal MI	5.1% vs. 11.0%

Ann Intern Med. 2018;168:237-44.

Severance Cardiovascular Hospital Registry

2179 pts, single center in Korea from November 2006 to December 2016

Continuation 1242 (57%) vs. Discontinuation 937 (43%)

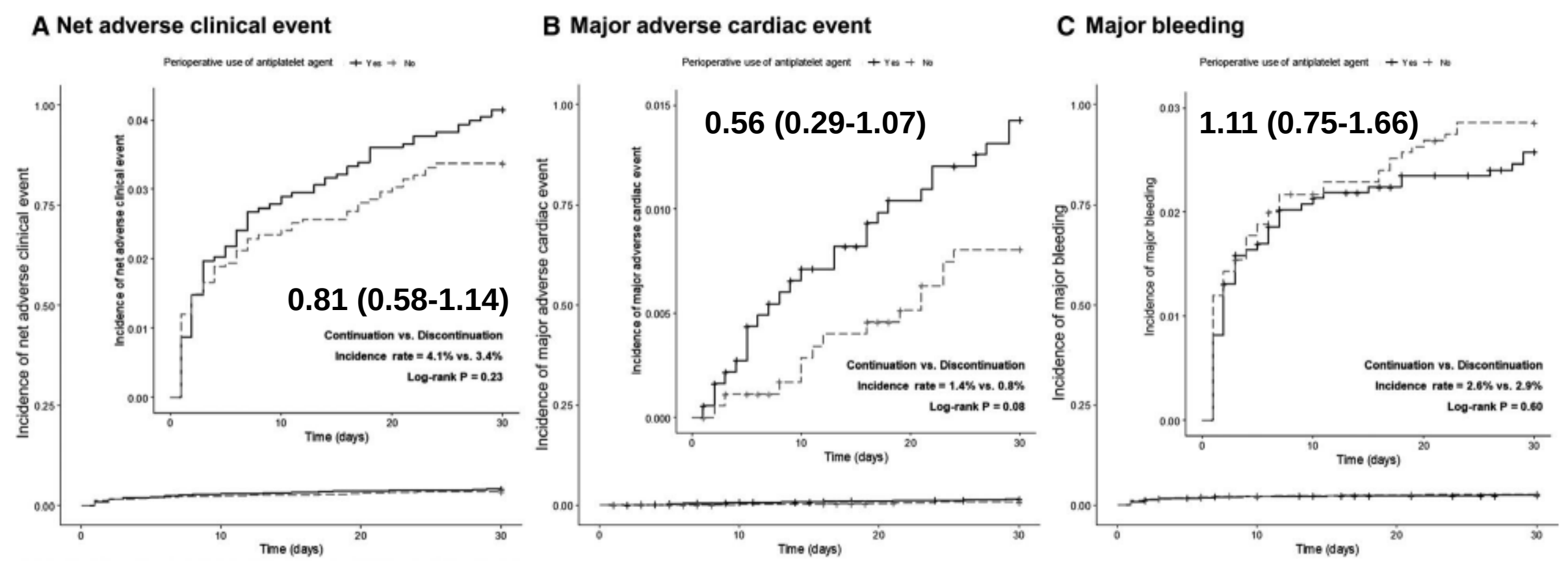


Am J Cardiol. 2019; 123(9):1414-1421.

KOMATE registry

3,582 pts, 9 Centers in Korea from May 2008 to October 2018

Continuation 1,832 (51%) vs. Discontinuation 1,750 (49%)



J Am Heart Assoc. 2020;9:e016218.

2022 ESC guideline

Recommendations	Class[a]	Level[b]
It is recommended to delay elective NCS until 6 months after elective PCI and 12 months after an ACS.[264,271]	I	A
After elective PCI, it is recommended to delay time-sensitive NCS until a minimum of 1 month of DAPT treatment has been given.[266,271,288,289]	I	B
In patients with a recent PCI scheduled for NCS, it is recommended that management of antiplatelet therapy is discussed between the surgeon, anaesthesiologist, and cardiologist.	I	C
In high-risk patients with a recent PCI (e.g. STEMI patients or high-risk NSTE-ACS patients), a DAPT duration of at least 3 months should be considered before time-sensitive NCS.	IIa	C
Continuation of medication		
In patients with a previous PCI, it is recommended to continue aspirin peri-operatively if the bleeding risk allows.[244]	I	B
Recommended time interval for drug interruption before NCS		
If interruption of $P2Y_{12}$ inhibitor is indicated, it is recommended to withhold ticagrelor for 3–5 days, clopidogrel for 5 days, and prasugrel for 7 days prior to NCS.[262–264]	I	B
For patients undergoing high bleeding risk surgery (e.g. intracranial, spinal neurosurgery, or vitreoretinal eye surgery), it is recommended to interrupt aspirin for at least 7 days pre-operatively.	I	C
In patients without a history of PCI, interruption of aspirin at least 3 days before NCS may be considered if the bleeding risk outweighs the ischaemic risk, to reduce the risk of bleeding.[243]	IIb	B
Resumption of medication		
If antiplatelet therapy has been interrupted before a surgical procedure, it is recommended to restart therapy as soon as possible (within 48 h) post-surgery, according to interdisciplinary risk assessment.	I	C

2016 ACC/AHA guideline

COR	LOE	Recommendations
I	B-NR	Elective noncardiac surgery should be delayed 30 days after BMS implantation and optimally 6 months after DES implantation (101-103,143-146).
I	C-EO	In patients treated with DAPT after coronary stent implantation who must undergo surgical procedures that mandate the discontinuation of $P2Y_{12}$ inhibitor therapy, it is recommended that aspirin be continued if possible and the $P2Y_{12}$ platelet receptor inhibitor be restarted as soon as possible after surgery.
IIa	C-EO	When noncardiac surgery is required in patients currently taking a $P2Y_{12}$ inhibitor, a consensus decision among treating clinicians as to the relative risks of surgery and discontinuation or continuation of antiplatelet therapy can be useful.
IIb	C-EO	Elective noncardiac surgery after DES implantation in patients for whom $P2Y_{12}$ inhibitor therapy will need to be discontinued may be considered after 3 months if the risk of further delay of surgery is greater than the expected risks of stent thrombosis.
III: Harm	B-NR	Elective noncardiac surgery should not be performed within 30 days after BMS implantation or within 3 months after DES implantation in patients in whom DAPT will need to be discontinued perioperatively (101-103,143-146).

Gap in current evidence

- Observational studies: selection bias
- Subgroup analysis of POISE-2: Small sample size (470 pts) and subgroup analysis

ASSURE DES Randomized Trial

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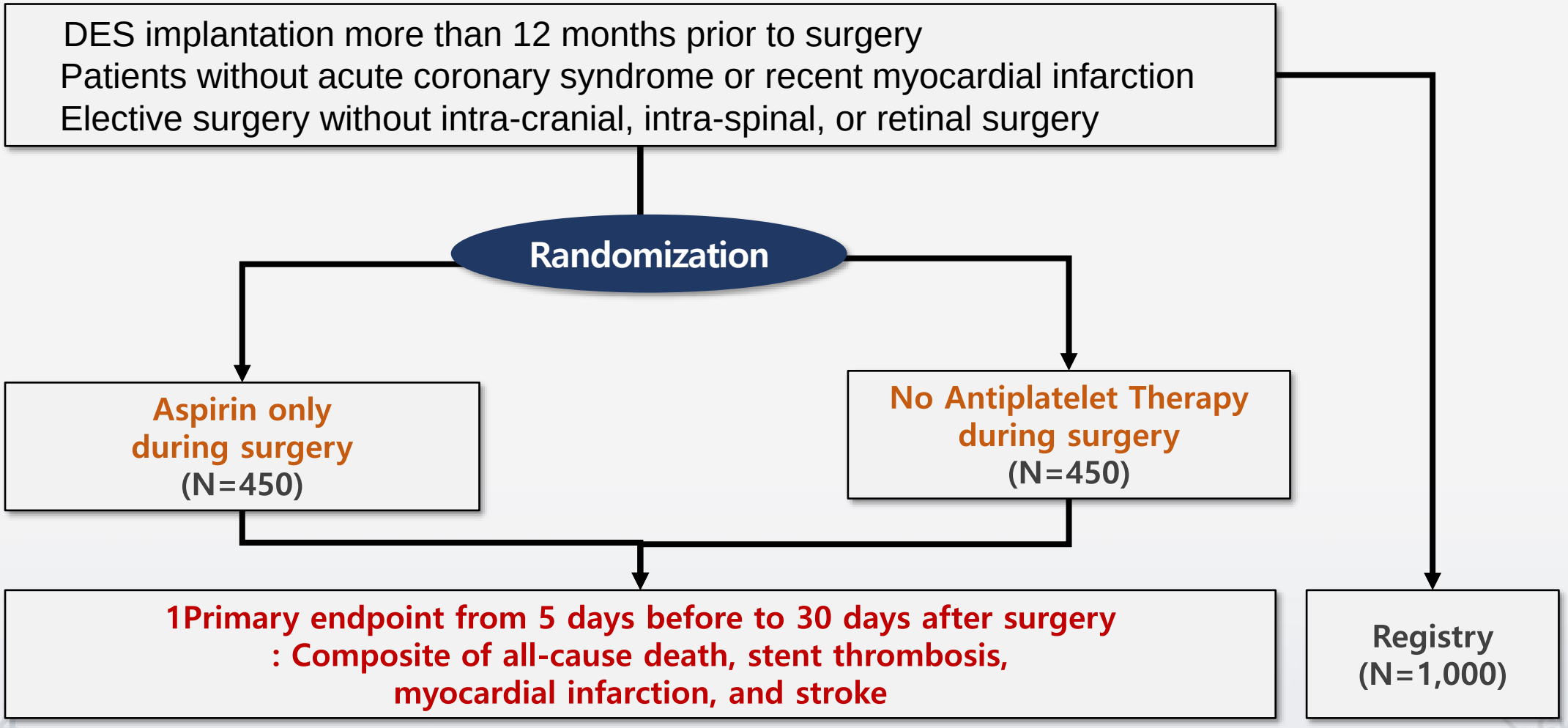


ASSURE DES Randomized Trial

Objectives

- This trial compared the clinical efficacy and safety of antiplatelet therapy in patients undergoing non-cardiac surgery for more than 12 months after PCI with DES.
- This trial compared outcome of discontinued antiplatelet treatment group and aspirin-alone treatment group.

Primary endpoint

- The Composite of Death, Stent Thrombosis, MI, Stroke (5 days before and 30 days after Non-cardiac Surgery)

ASSURE DES Randomized Trial

Inclusion Criteria

1) Men and women aged 19 years or more
2) Patients who implanted ≥ 1 coronary drug-eluting stents
3) Patients scheduled for surgery at more than 12 months after PCI
4) Patients scheduled for elective non-cardiac surgery under general anesthesia

Exclusion Criteria

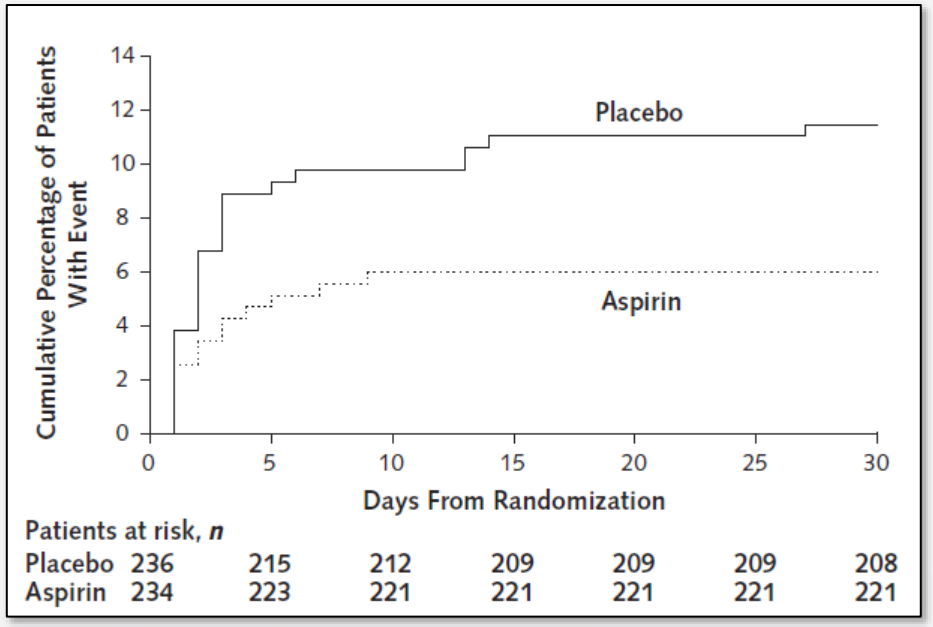
1) Patient who currently have ACS or MI within 1 month
2) Patient with dyspnea (NYHA III~IV) due to severe LV dysfunction (EF ≤30%) or severe VHD
3) Patient who have Intolerance for aspirin
4) Patient who need for anticoagulation therapy
5) Emergent operation
6) Cardiac surgery
7) High bleeding risk op. (Intra-cranial, Intra-spinal, Retinal surgery)
8) Pregnant and/or lactating women

ASSURE DES Randomized Trial

Sample Size

▶ Based on the results of the study in the POISE-2 trial, the primary endpoints of each treatment group were estimated. We will randomize 900 patients over 12 months after coronary stenting by 1:1 fashion, a) aspirin-alone treatment, b) discontinuation of antiplatelet agents. The assumed primary endpoint event rate was assumed 6.0% in aspirin-only therapy group and 11.5% in antiplatelet therapy discontinuation group. We estimated that enrollment of 900 patients would provide the study with 80% power to establish superiority of aspirin-only therapy in primary end point at 30 days, at a two-side type I error rate of 0.05.

POISE-2 (Ann Intern Med. 2018;168:237-244)



ASSURE DES Randomized Trial

TRIAL PROCEDURES AND FOLLOW-UP

- Patients are randomized to Aspirin-alone or Non-Antiplatelet group.
- Aspirin-alone group takes only aspirin from 5 days before surgery.
- Patients on a single P2Y12 inhibitor change to aspirin from 5d before operation.
- Patients on DAPT change to single aspirin from 5 days before operation.
- DAPT is resumed postoperatively as soon as possible (if possible, POD #2)
- Non-antiplatelet group discontinue all antiplatelet agent from 5 days before op. Antiplatelet agent is resumed as soon as possible after op.
- All patients are followed up by OPD visits or telephone at 30 day after surgery.

Current status

- From March 2017 through March 2024, a total of 900 patients were enrolled.

- This year, the primary results will be available.

Conclusion

- The ASSURE-DES trial is a prospective, multicenter, and randomized study to compare the safety and efficacy of aspirin cessation or not in perioperative period of non-cardiac surgery in patient who have undergone PCI with DES for more than 12 months.

- It may help to determine optimal antiplatelet therapy in patient who underwent PCI with DES before non-cardiac surgery.