

I prefer antiplatelet therapy with NOAC after 1 year in AF patients undergoing PCI

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Disclosure

▶ Grant support

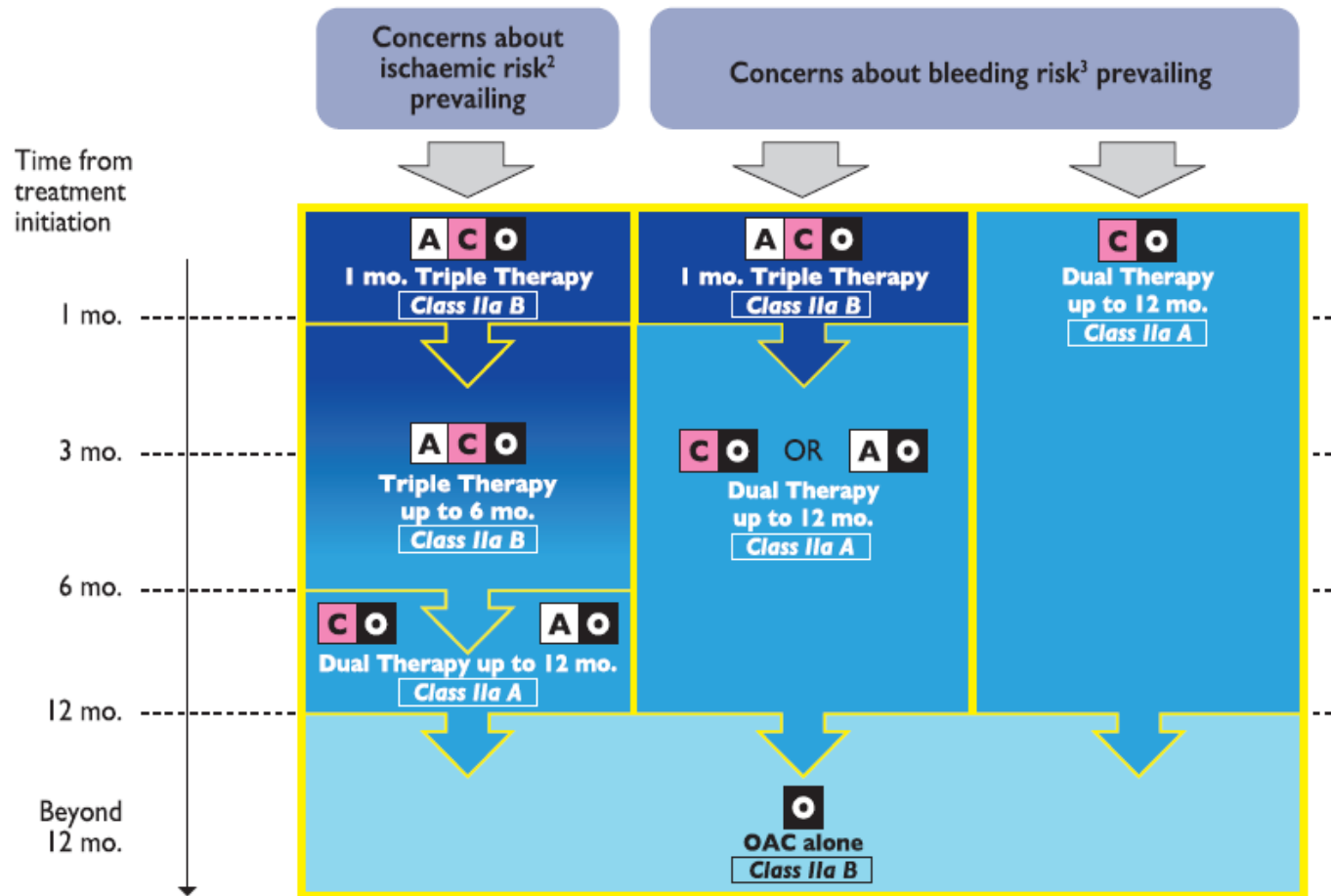
- Korean Society of Interventional Cardiology
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- Abbott Vascular, Biotronik, Boston Scientific, Daiichi Sankyo, and Medtronic

▶ Consulting Fees/Honoraria

- Abbott Vascular, Astra Zeneca, Biotronik, Biometrics, Daiichi Sankyo, Pfizer, and Sanofi-Aventis



Patients with an indication for oral coagulation undergoing PCI: ESC guideline 2017



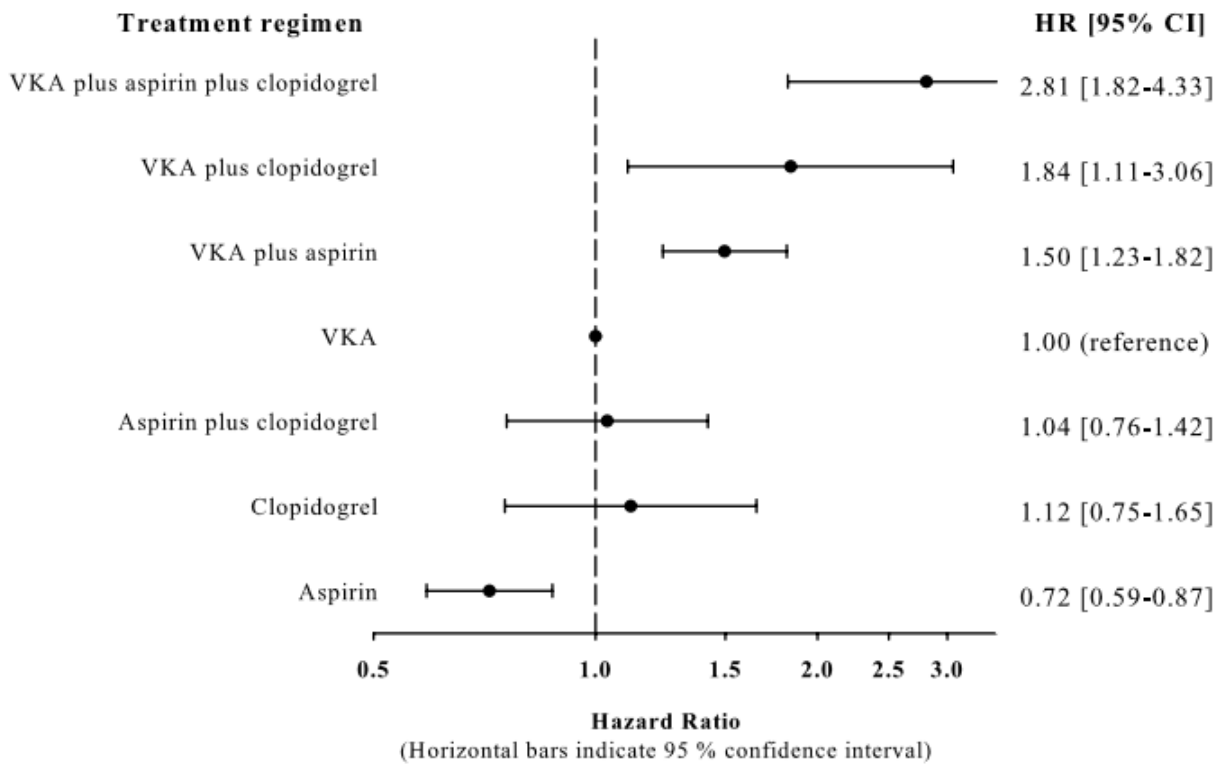
A = Aspirin **C** = Clopidogrel **O** = Oral anticoagulation

- ▶ OAC alone is recommended beyond 12 months after PCI in patients requiring anticoagulation.
- ▶ However, data are limited supporting this recommendation.
- ▶ In real world practice, substantial patients with A fib receive an antiplatelet with OAC beyond 12 months after PCI.

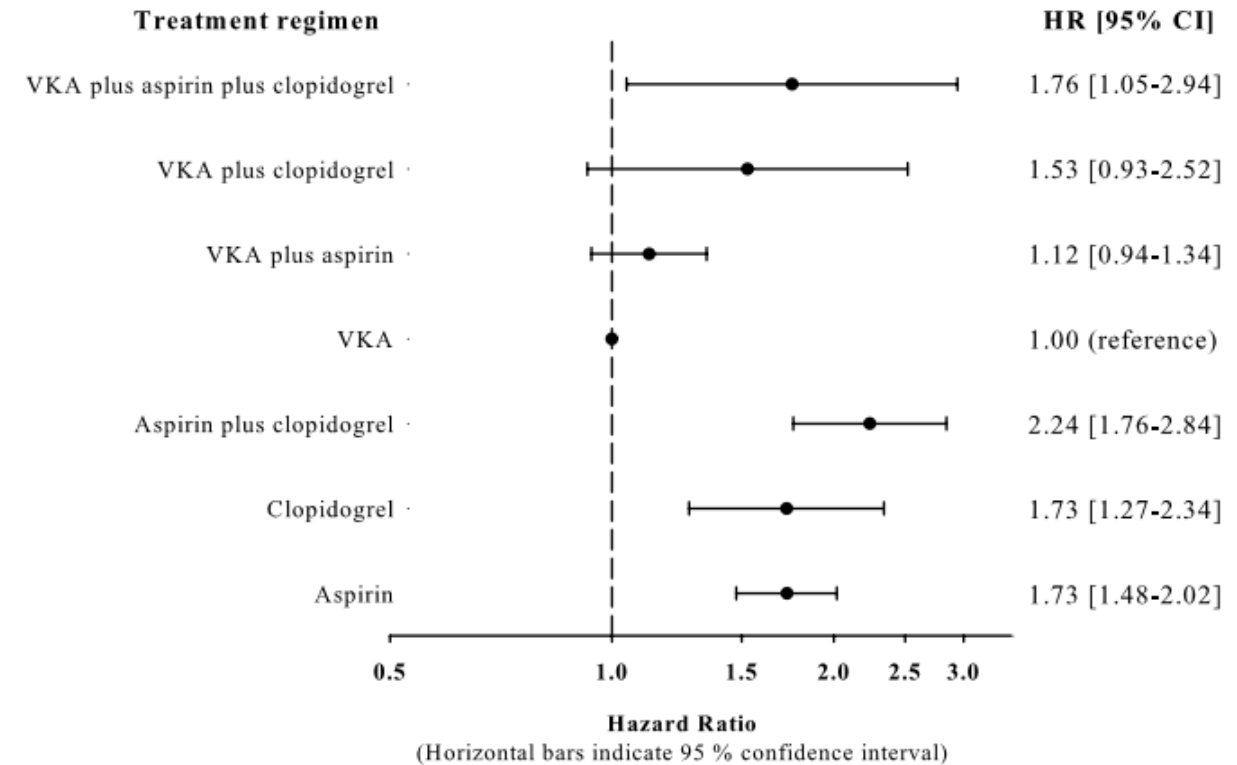


Danish registry data

ISTH major/CRNM bleeding



Coronary death or MI





Antithrombotic Treatment

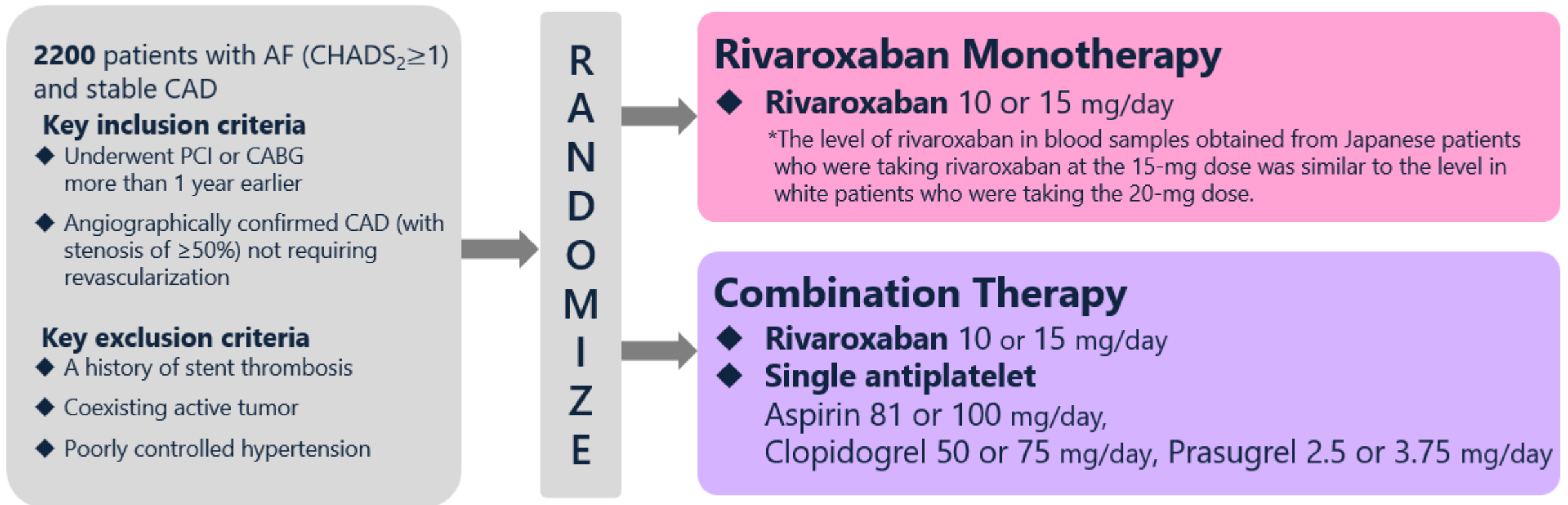
Characteristics	Including VKA			
	VKA (n=950)	VKA Plus Aspirin (n=1471)	VKA Plus Clopidogrel (n=322)	VKA Plus Aspirin Plus Clopidogrel (n=500)
Female	360 (38)	460 (31)	96 (30)	101 (20)
Age, y, mean (SD)	73.2 (10.0)	73.6 (9.0)	72.6 (8.1)	71.0 (8.4)
Previous MI	804 (85)	1104 (75)	141 (44)	211 (42)
With PCI performed*	57 (79)	170 (15)	77 (55)	108 (51)
With stent implantation*	44 (5)	134 (12)	70 (50)	96 (45)
Previous PCI without MI	146 (15)	367 (25)	181 (56)	289 (58)
With stent implantation*	112 (77)	255 (69)	168 (93)	272 (94)

▶ Limitations

- Retrospective non-randomized study
- Moderate sample size, at best (VKA = 169 and VAK + SAP = 670)
- No angiographic and procedural data (ex. multivessel disease, number and size of stents, and complexity of PCI)

Atrial Fibrillation and Ischemic events with Rivaroxaban in patients with stable coronary artery disease: AFIRE Study

A multicenter, prospective, randomized, open-label, parallel-group trial



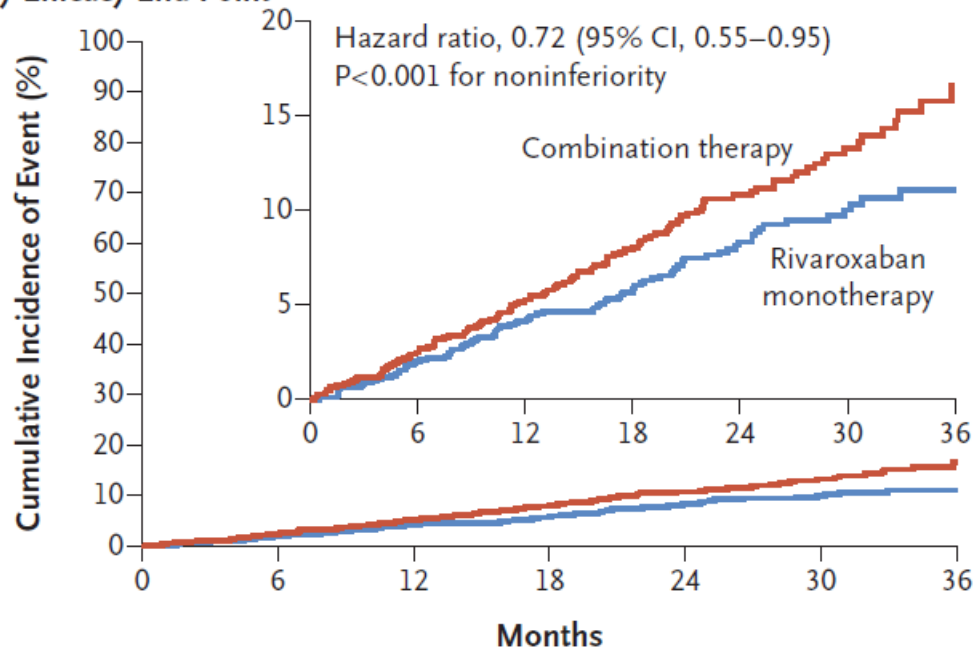


AFIRE: Outcomes

Stroke, systemic embolism, MI, unstable angina requiring revascularization, or death

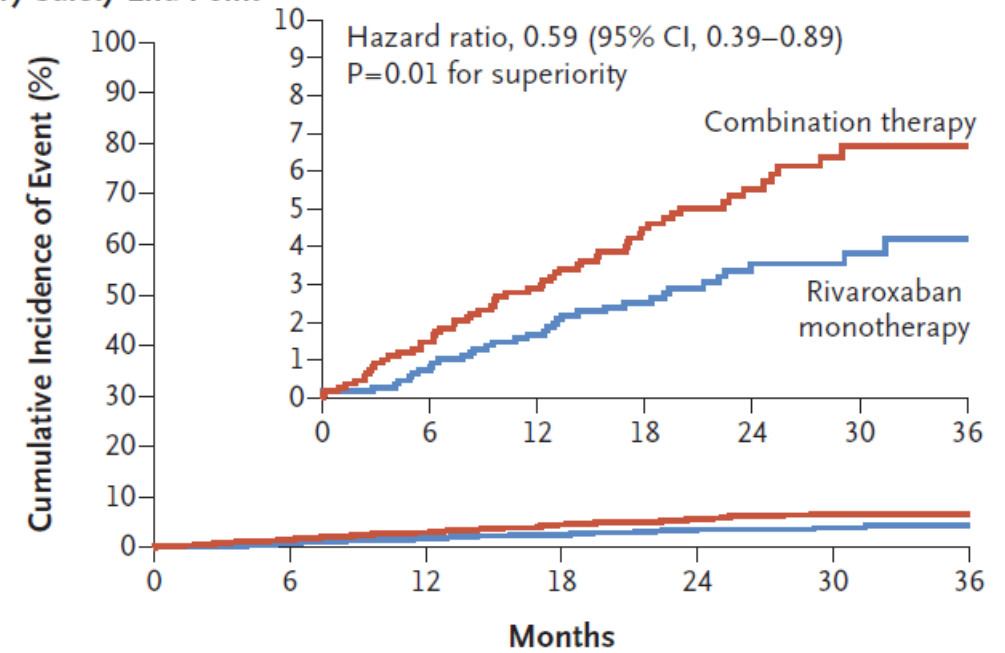
ISTH major bleeding

A Primary Efficacy End Point



No. at Risk	0	6	12	18	24	30	36
Combination therapy	1108	1057	962	754	499	292	80
Rivaroxaban monotherapy	1107	1071	984	774	518	309	89

B Primary Safety End Point

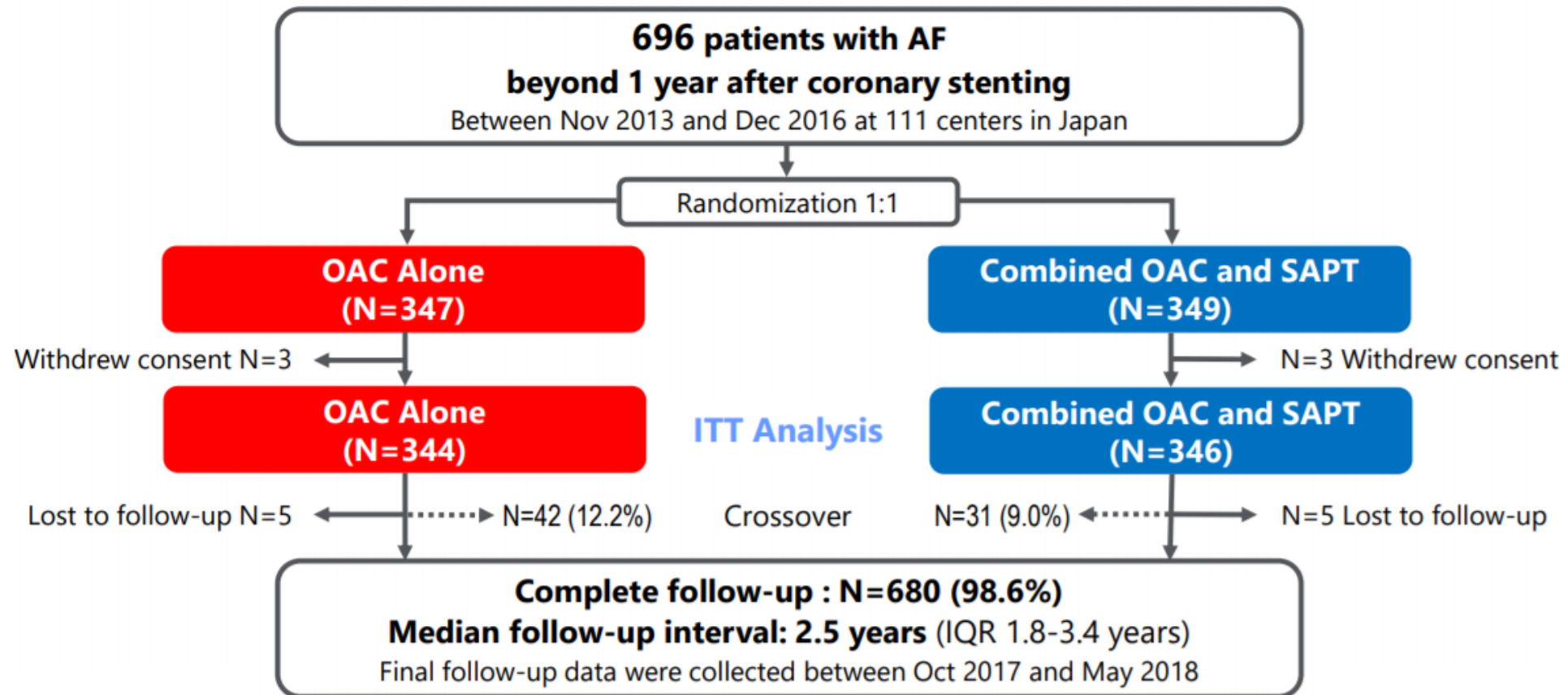


No. at Risk	0	6	12	18	24	30	36
Combination therapy	1099	1055	962	750	506	294	80
Rivaroxaban monotherapy	1099	1074	994	786	526	312	89



OAC-ALONE trial: Study design

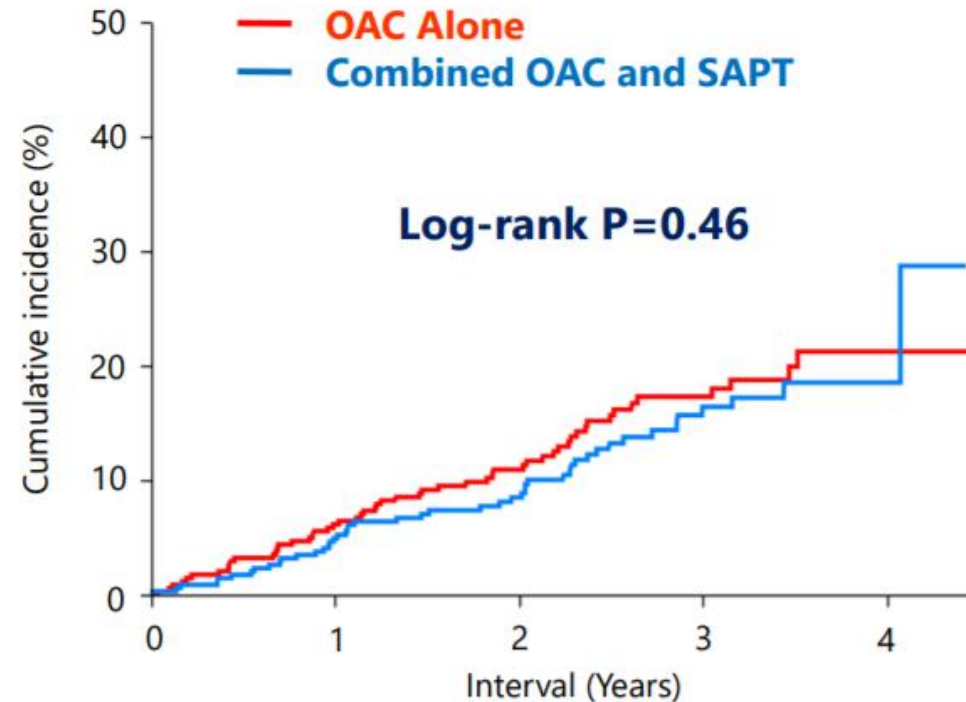
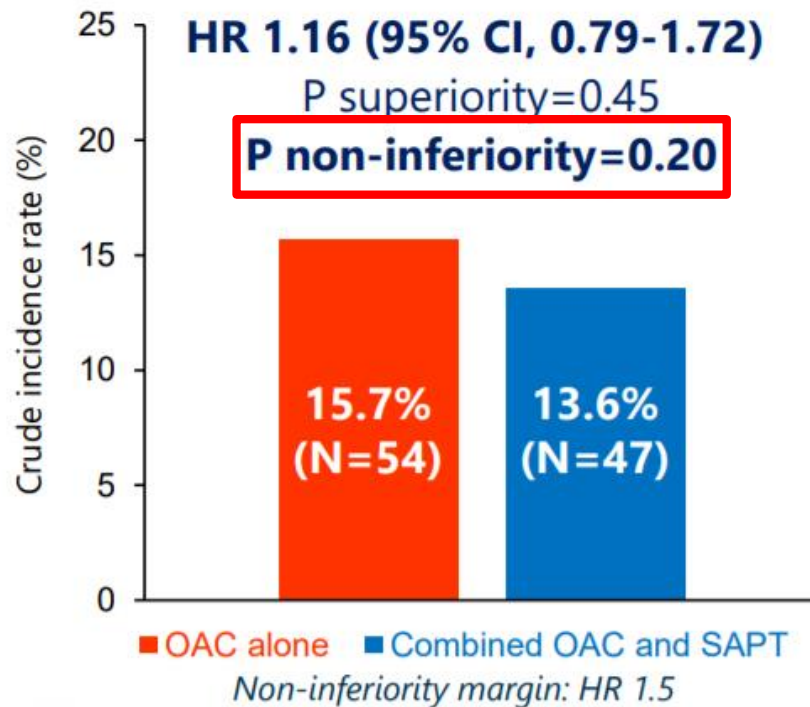
Prospective, multicenter, open-label, randomized, non-inferiority trial





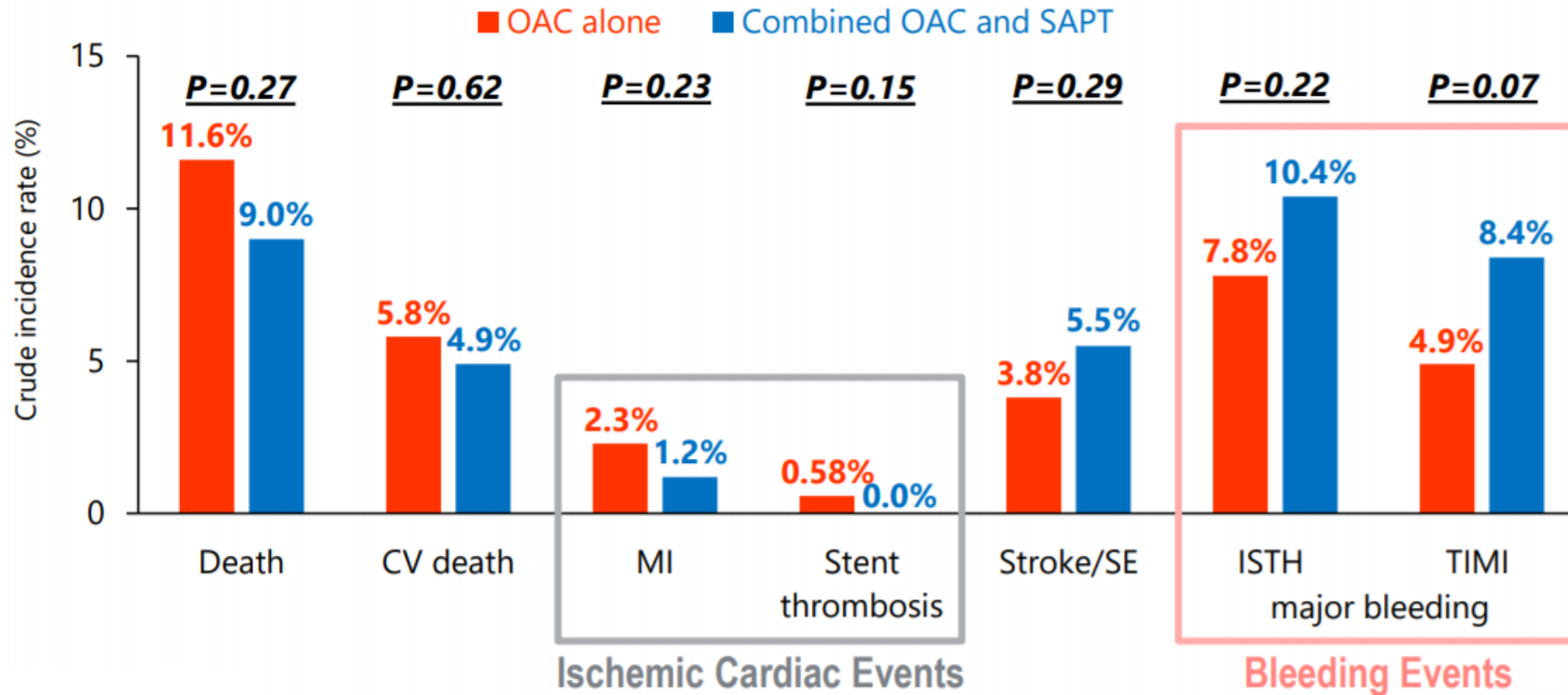
OAC-ALONE trial: Primary end point

Death, MI, Stroke, or SE





OAC-ALONE trial: Individual outcomes





AFIRE vs. OAC-ALONE

Procedural characteristics	AFIRE-Stent		OAC-ALONE		ASAN registry
	Rivaroxaban Monotherapy (N=723)	Combination Therapy (N=721)	OAC Alone (N=344)	Combined OAC and APT (N=346)	A fib (N=711)
Number of stents	-	-	2 (1-3)	2 (1-3)	1.9±1.2
Type of stent	-	-			
Drug-eluting	500 (69.2)	477 (66.2)	246 (71.7)	240 (70.6)	711 (100.0)
Bare metal	171 (23.7)	171 (23.7)	97 (28.3)	100 (29.4)	0 (0.0)
Left main coronary stenting	24 (3.1)	22 (3.1)	23 (6.7)	22 (6.4)	-
Multivessel stenting	-	-	119 (34.6)	119 (35.0)	-
Total stent length (mm)	-	-			49.2±32.4
Years from the last PCI	-	-	4.4 (1.8-7.7)	4.6 (2.4-7.4)	-



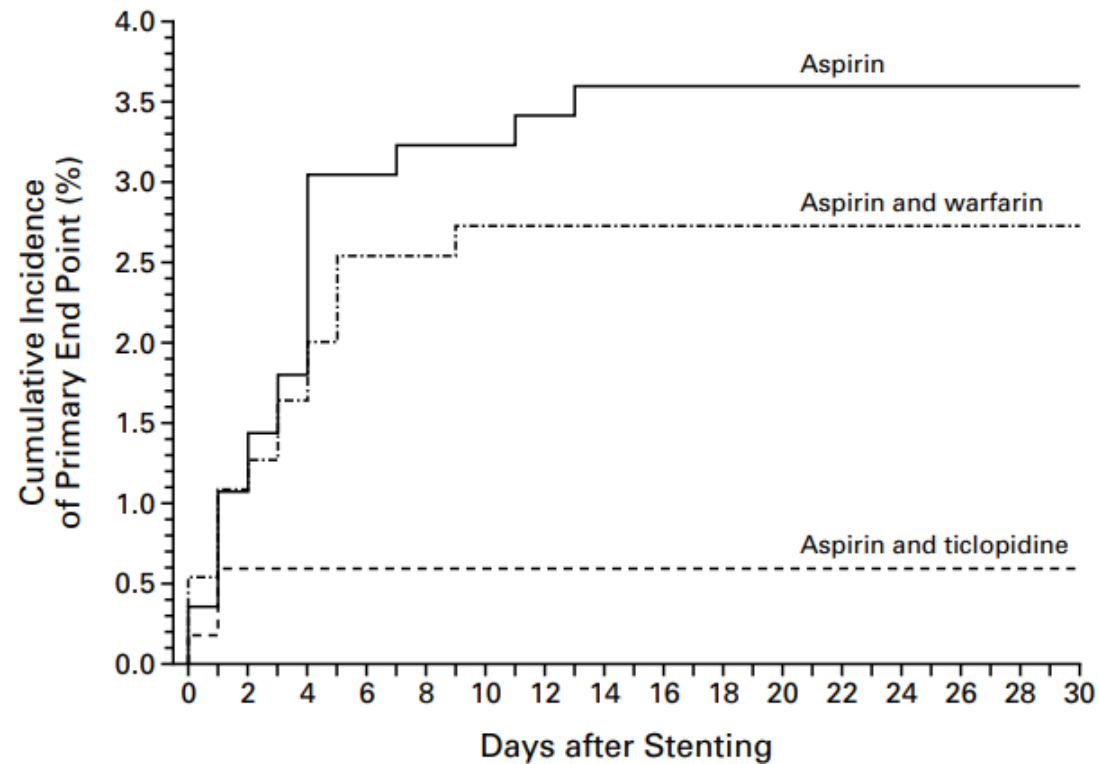
Limitation of the AFIRE trial

- ▶ Lack in lesion and procedural data
- ▶ Substantial proportion (11%) of patients did not complete the trial due to withdrawal of consent and loss of follow-up.
- ▶ Inclusion of revascularization in the primary end point, which might be problematic given the open label design.
- ▶ Underdose of rivaroxaban compared with globally approved dose
- ▶ The reductions in the rate of ischemic events and death from any cause with rivaroxaban monotherapy are difficult to explain on the basis of the biologic effects of antithrombotic therapy. → Play of chance.



STARS trial

Death, MI, stent thrombosis, or TLR



EVENT	RELATIVE RISK (95% CI) AS COMPARED WITH ASPIRIN ALONE	P VALUE	RELATIVE RISK (95% CI) AS COMPARED WITH ASPIRIN AND WARFARIN	P VALUE
Primary end point	0.15 (0.05–0.43)	<0.001	0.20 (0.07–0.61)	0.01
Death	—	—	—	—
Revascularization of target lesion	0.16 (0.06–0.46)	0.001	0.22 (0.07–0.66)	0.02
Angiographically evident thrombosis	0.19 (0.06–0.57)	0.001	0.20 (0.07–0.61)	0.01
Recurrent myocardial infarction	0.20 (0.07–0.62)	0.014	0.27 (0.08–0.90)	0.11
Neutropenia or thrombocytopenia	3.06 (0.36–26.2)	0.74	3.02 (0.35–25.91)	0.75
Hemorrhagic complications	3.06 (1.57–5.97)	0.002	0.88 (0.55–1.43)	0.99
Vascular surgical complications	5.61 (1.49–21.16)	0.02	1.01 (0.44–2.30)	0.99



Meta-analyses of 4 A fib-PCI trials

Myocardial Infarction

Study or Subgroup	NOAC DAT		VKA TAT		Weight	Risk Ratio M-H, Random, 95% CI
	Events	Total	Events	Total		
AUGUSTUS	38	1153	34	1154	29.3%	1.12 (0.71, 1.76)
ENTRUST AF-PCI	29	751	23	755	21.0%	1.27 (0.74, 2.17)
PIONEER AF-PCI	19	694	21	695	16.2%	0.91 (0.49, 1.67)
RE-DUAL PCI	70	1744	29	981	33.5%	1.36 (0.89, 2.08)
Total (95% CI)		4342		3585	100.0%	1.18 (0.93, 1.52)

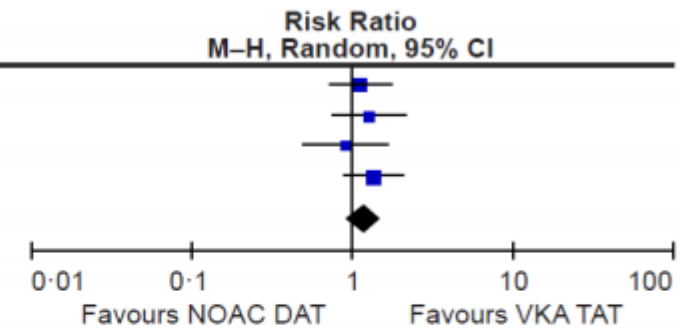
Total events

156

107

Heterogeneity: $\tau^2 = 0.00$; $\text{Chi}^2 = 1.25$, $\text{df} = 3$ ($P = 0.74$); $I^2 = 0\%$

Test for overall effect: $Z = 1.34$ ($P = 0.18$)



Stent Thrombosis

Study or Subgroup	NOAC DAT		VKA TAT		Weight	Risk Ratio M-H, Random, 95% CI
	Events	Total	Events	Total		
AUGUSTUS	21	1153	12	1154	40.0%	1.75 (0.87, 3.54)
ENTRUST AF-PCI	8	751	6	755	17.9%	1.34 (0.47, 3.84)
PIONEER AF-PCI	5	694	4	695	11.6%	1.25 (0.34, 4.64)
RE-DUAL PCI	22	1744	8	981	30.6%	1.55 (0.69, 3.46)
Total (95% CI)		4342		3585	100.0%	1.55 (0.99, 2.41)

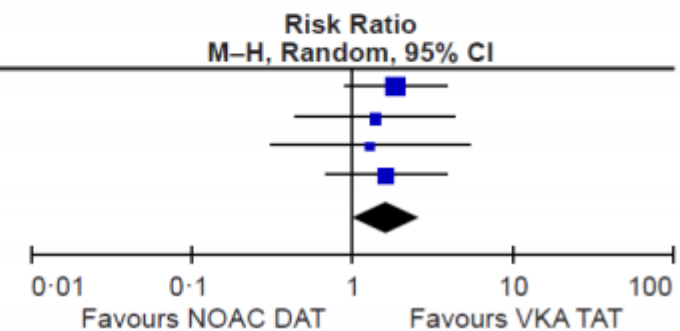
Total events

56

30

Heterogeneity: $\tau^2 = 0.00$; $\text{Chi}^2 = 0.29$, $\text{df} = 3$ ($P = 0.96$); $I^2 = 0\%$

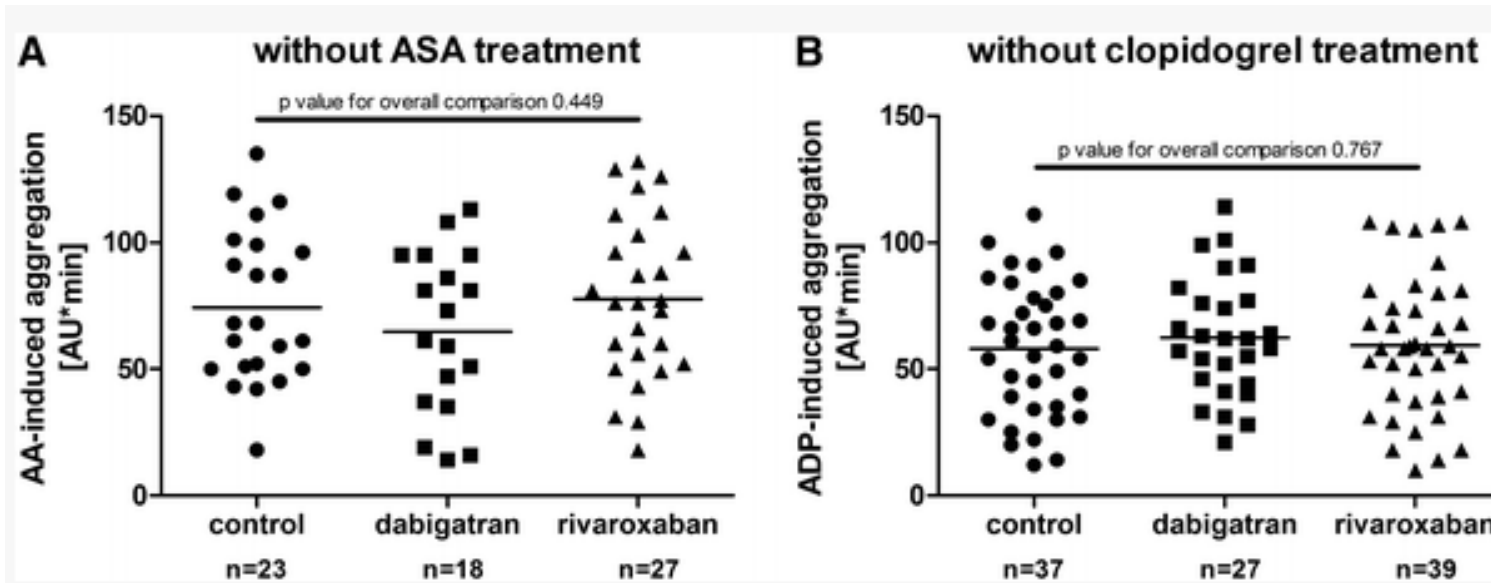
Test for overall effect: $Z = 1.92$ ($P = 0.06$)



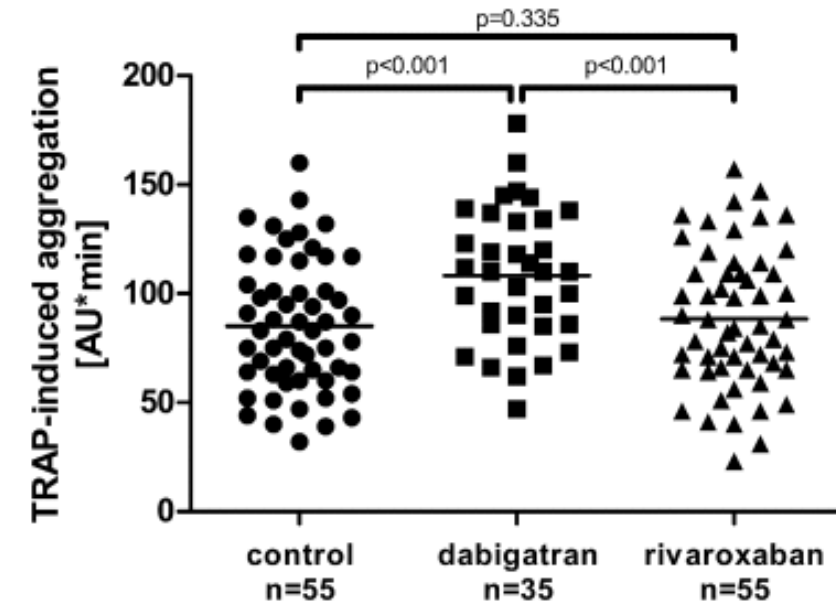


NOAC and platelet aggregation

AA- and ADP-induced platelet aggregation

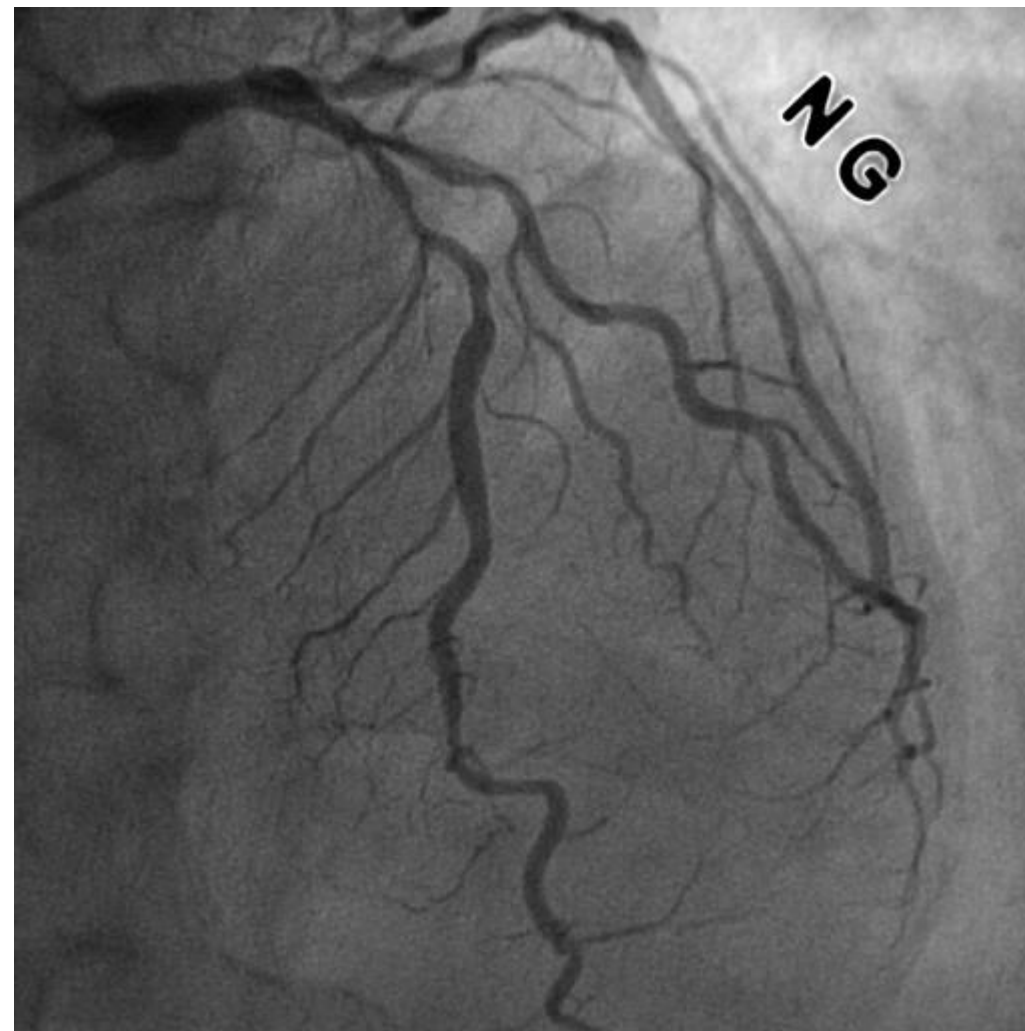
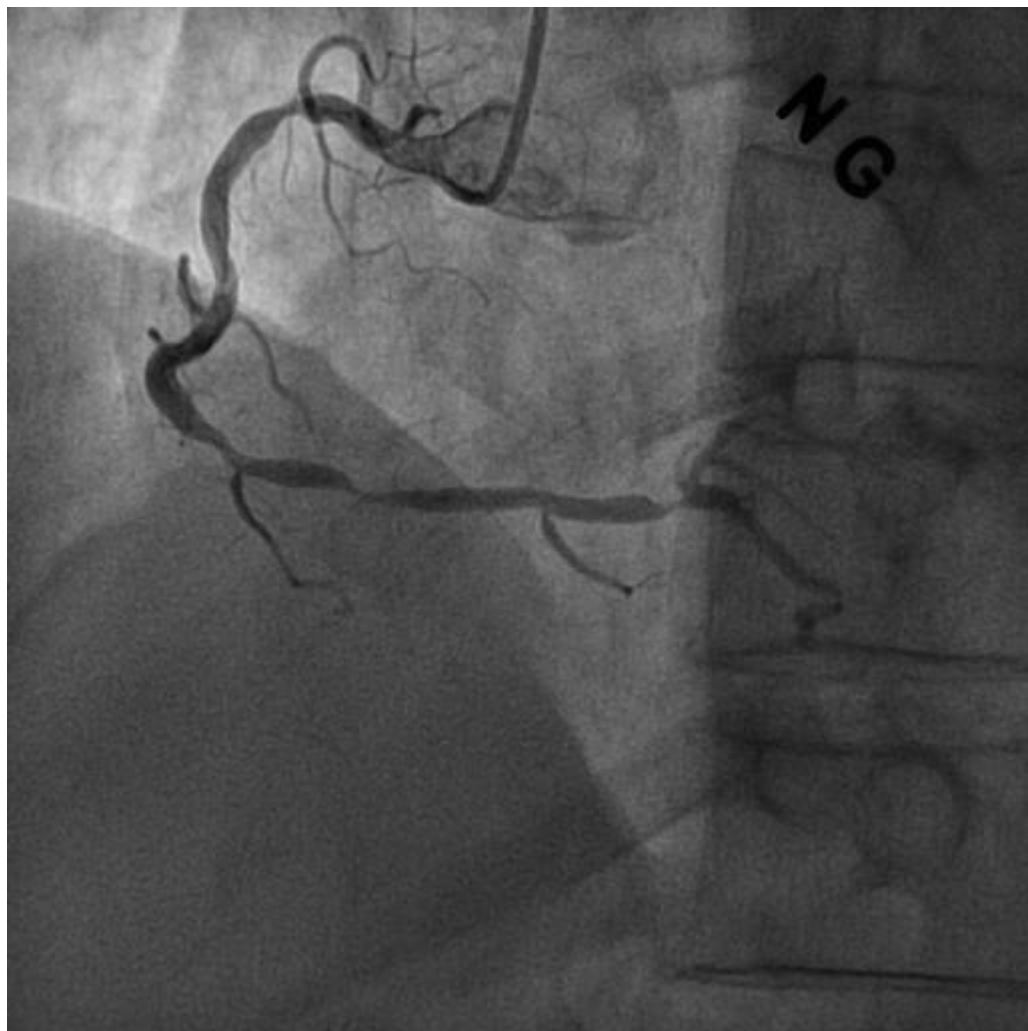


TRAP-induced platelet aggregation



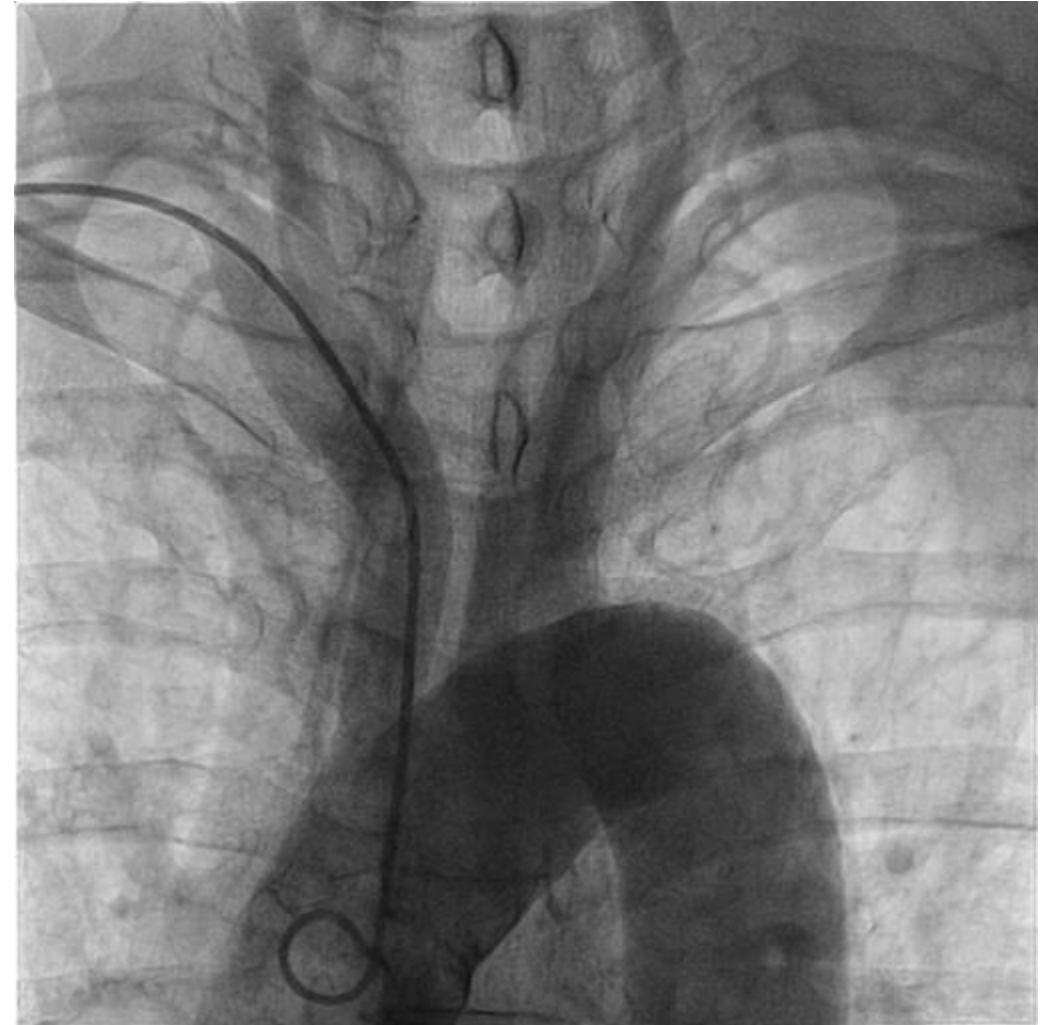
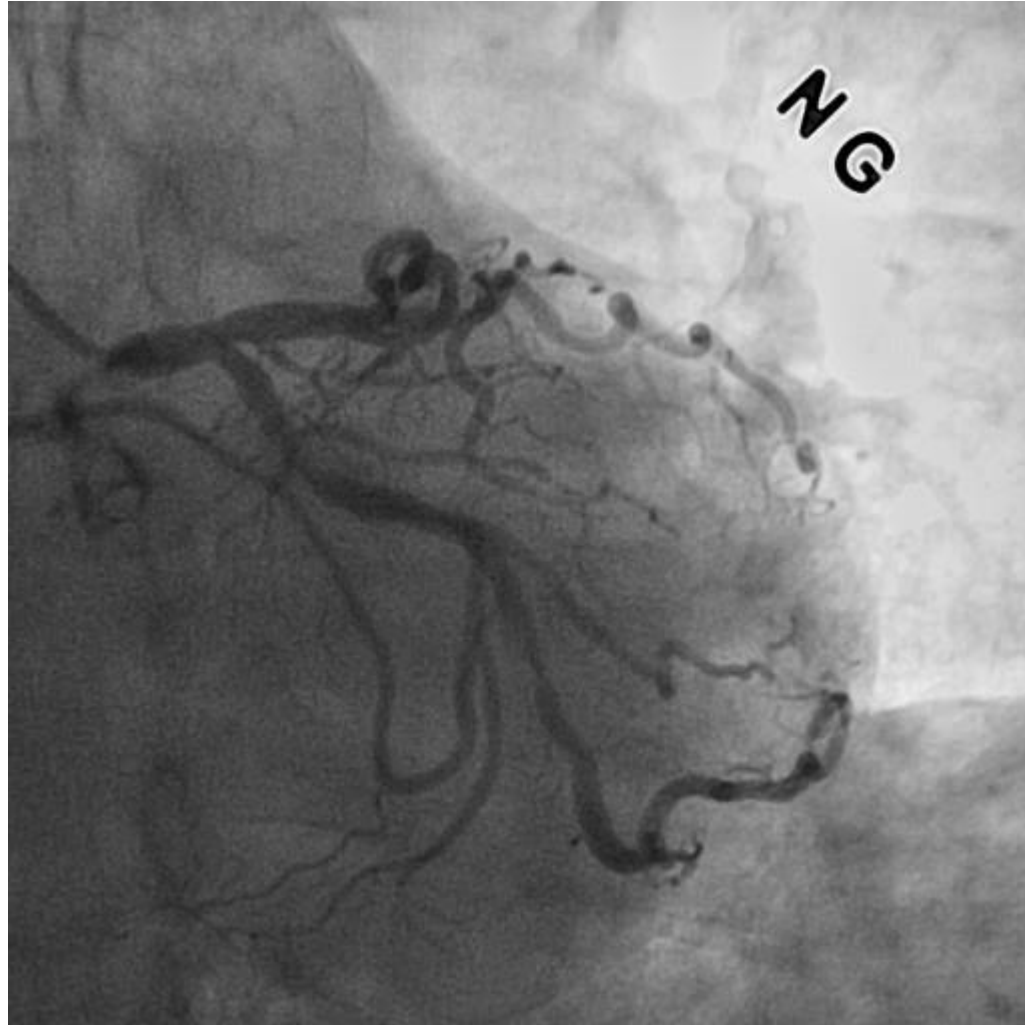


Case #1: M/65, stable IHD



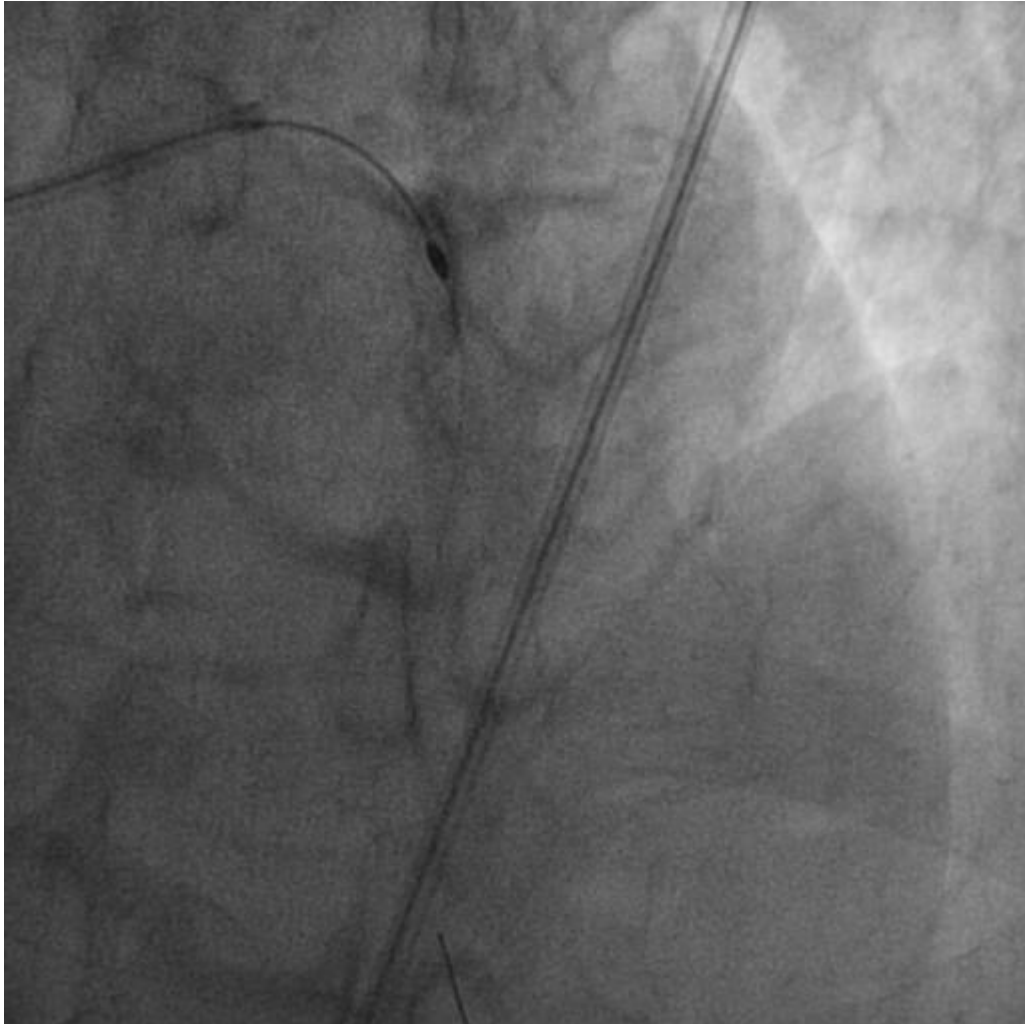


Case #1: 3VD → refused CABG



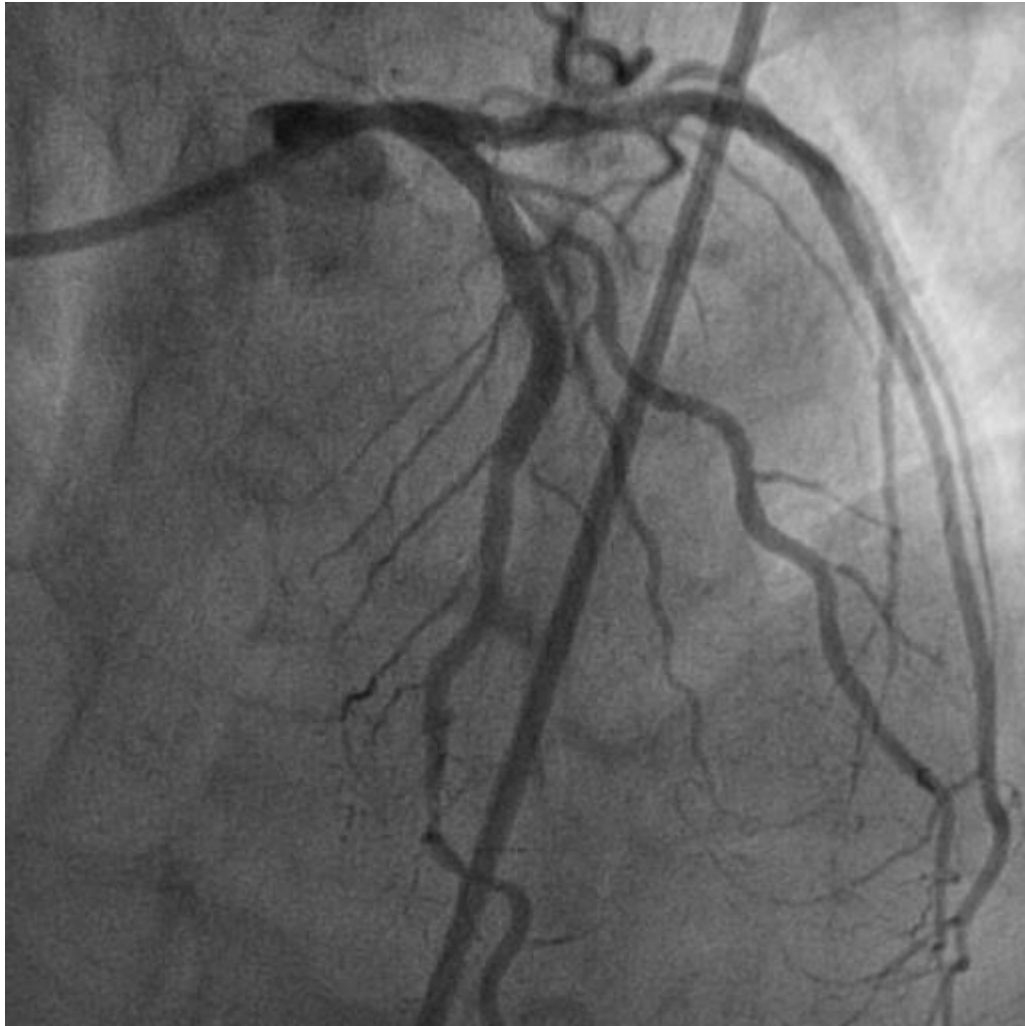


Case #1: Rotablation due to severe calcification





Case #1: Multivessel stenting





Case #1: Successful PCI



- ▶ DES*6 with Rotablation
- ▶ Aspirin + Clopidogrel
- ▶ At 10 months after the index procedure, A fib was documented.
 - CHA₂DS₂-VASC score: 4
 - Age, DM, HTN, and s/p EVAR
- ▶ NOAC + Clopidogrel (indefinitely unless major bleeding complications occur)

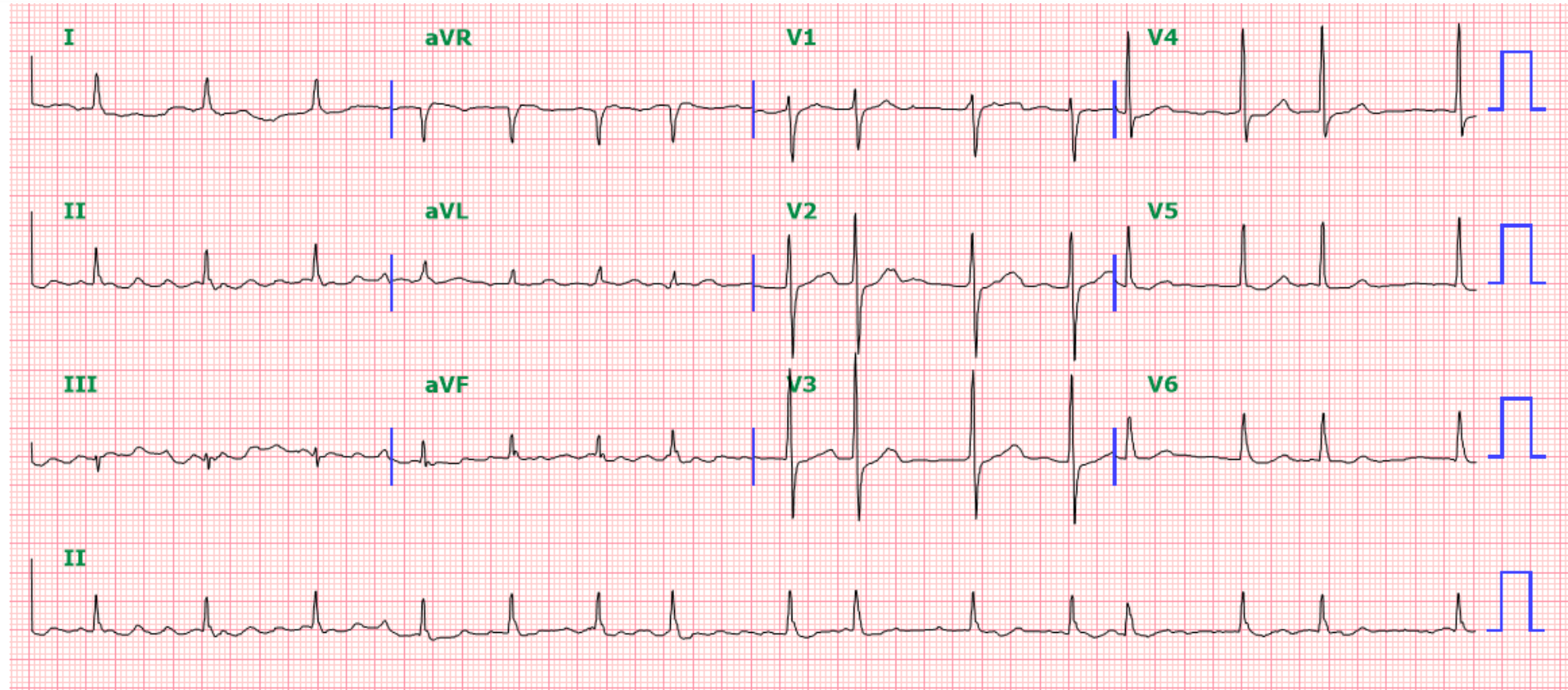


Are complex lesions rare? No!

- ▶ In several RCTs on DAPT duration, the proportion of complex PCI was reported to be 17.5% (1680 / 9577).
- ▶ However, complex PCI has been performed more frequently in real world practice than in RCTs.
- ▶ In our institutional PCI registry of DESs, complex lesions PCI comprised 45.1% of all PCI (6005 / 13313).
 - Choi KH, Song YB,...,Hahn JY. JACC Cardiovasc Interv. 2019;12:607-620.
- ▶ In Korean multicenter registries comparing BES vs. EES, complex PCI was performed in 57.3% of all procedures (1145 / 1999).
 - Song PS,...,Hahn JY. Korean Circ J. 2019;49:69-80.



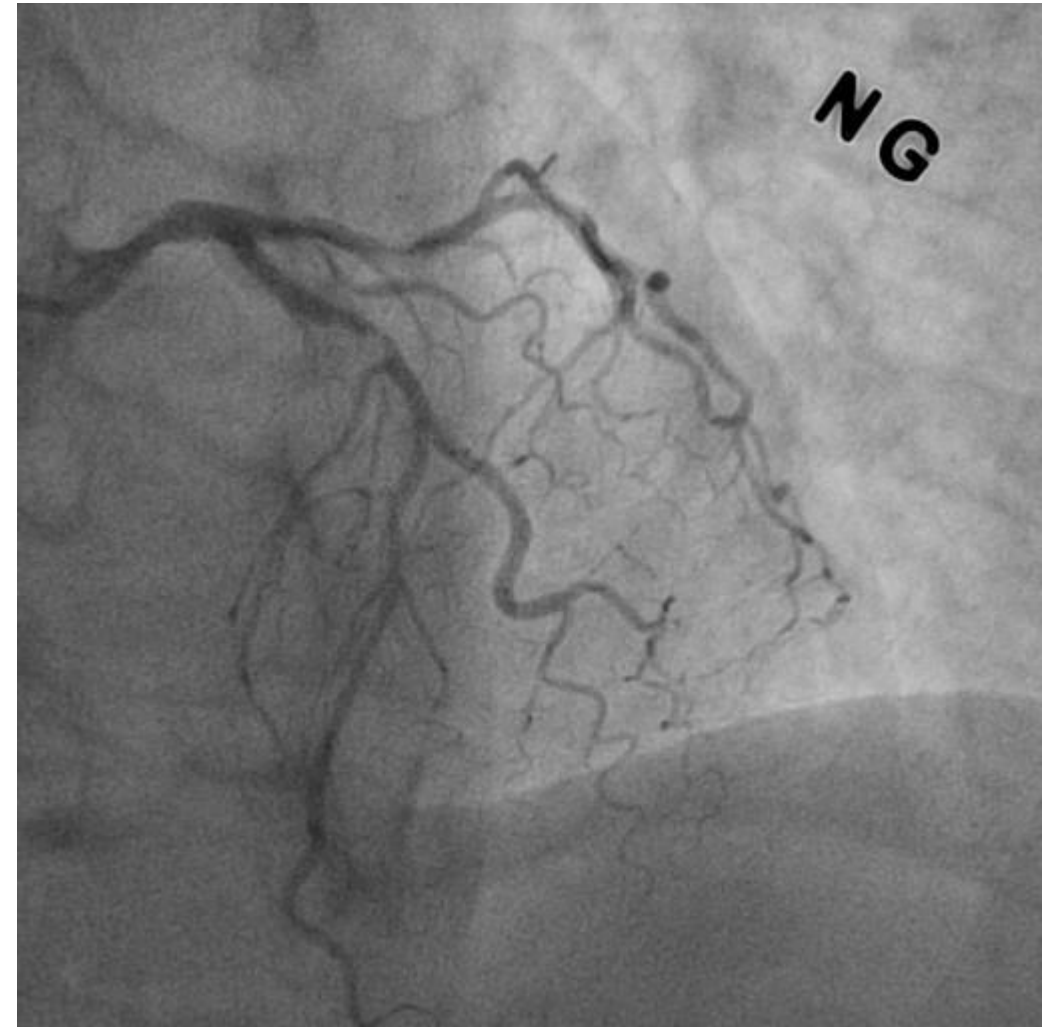
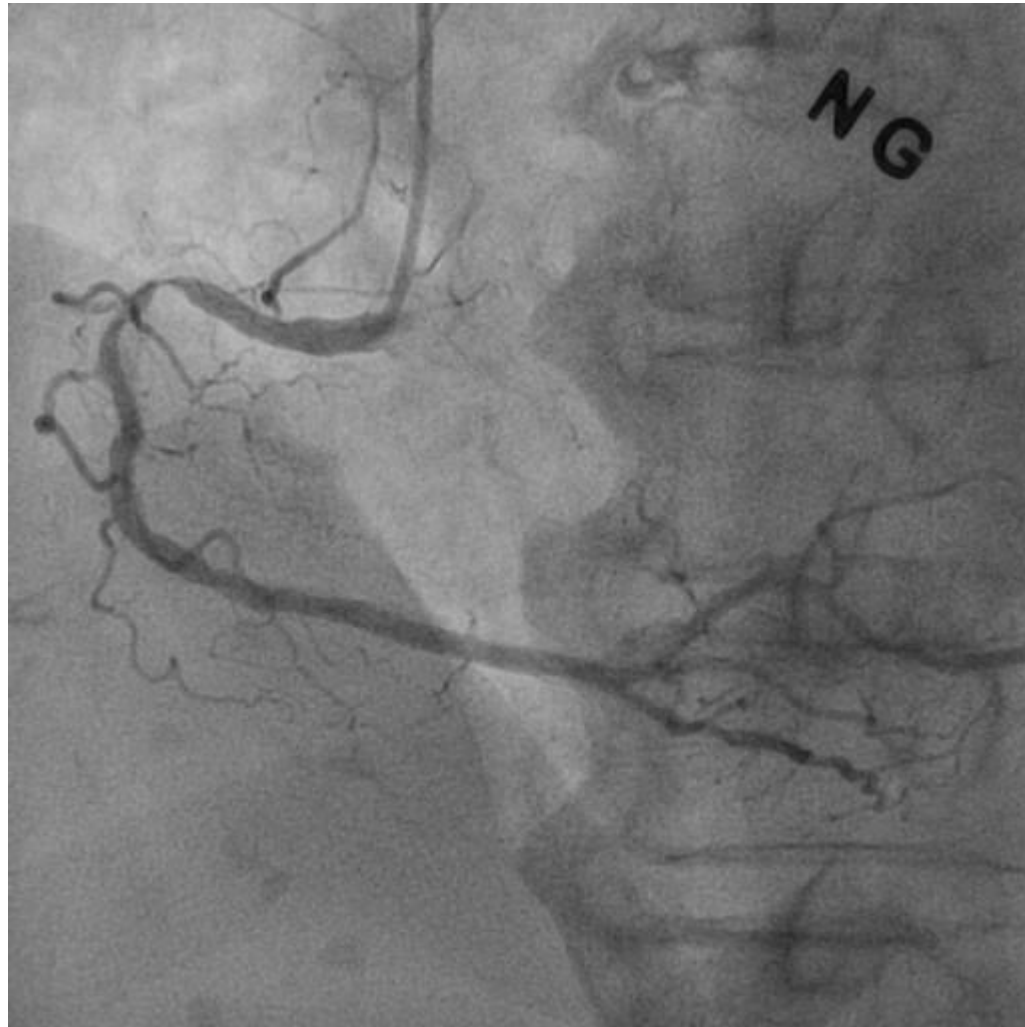
Case #2. F/66, NSTEMI and A fib



- ▶ CHA₂DS₂-VASC score : 5
 - Female, age, DM, HTN, and MI



Case #2. F/66, NSTEMI and A fib





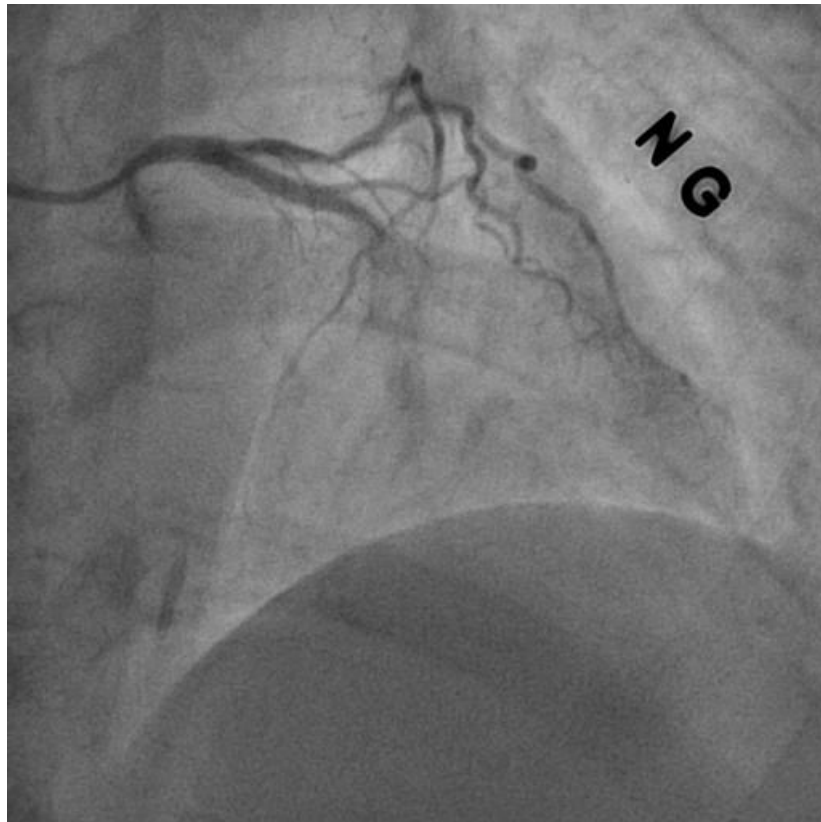
Case #2. Successful PCI





Anti-thrombotic treatment and follow-up

- ▶ Edoxaban 60 mg qd + Clopidogrel 75 mg qd
- ▶ At 9 months after the index PCI, the patient visited the ER due to dyspnea.





Many lesions were excluded in the RCTs.





Summary

- ▶ Guidelines recommend OAC alone beyond 12 months after PCI in patients requiring anticoagulation due to A fib.
- ▶ However, data are limited.
 - Only 2 trials with the modest sample size.
 - Lack in lesion and procedural characteristics.
- ▶ The optimal management for A fib and coronary artery disease (PCI) differs.
- ▶ Antiplatelet is needed beyond 1 year after PCI with OAC, at least in certain subset of patients (ex. ACS or complex PCI).

감사합니다.
Thank you for your attention.

