TCTAP, 2024. April 27
12:05 PM ~ 12:10 PM **(5 min)**
Presentation Room 1
Ongoing Trials from Asan Medical Center

EPIC-CAD Trial: Long-Term Antithrombotic Strategy in AF Patients with Stable CAD

Gi-Byoung Nam MD
Asan Medical Center

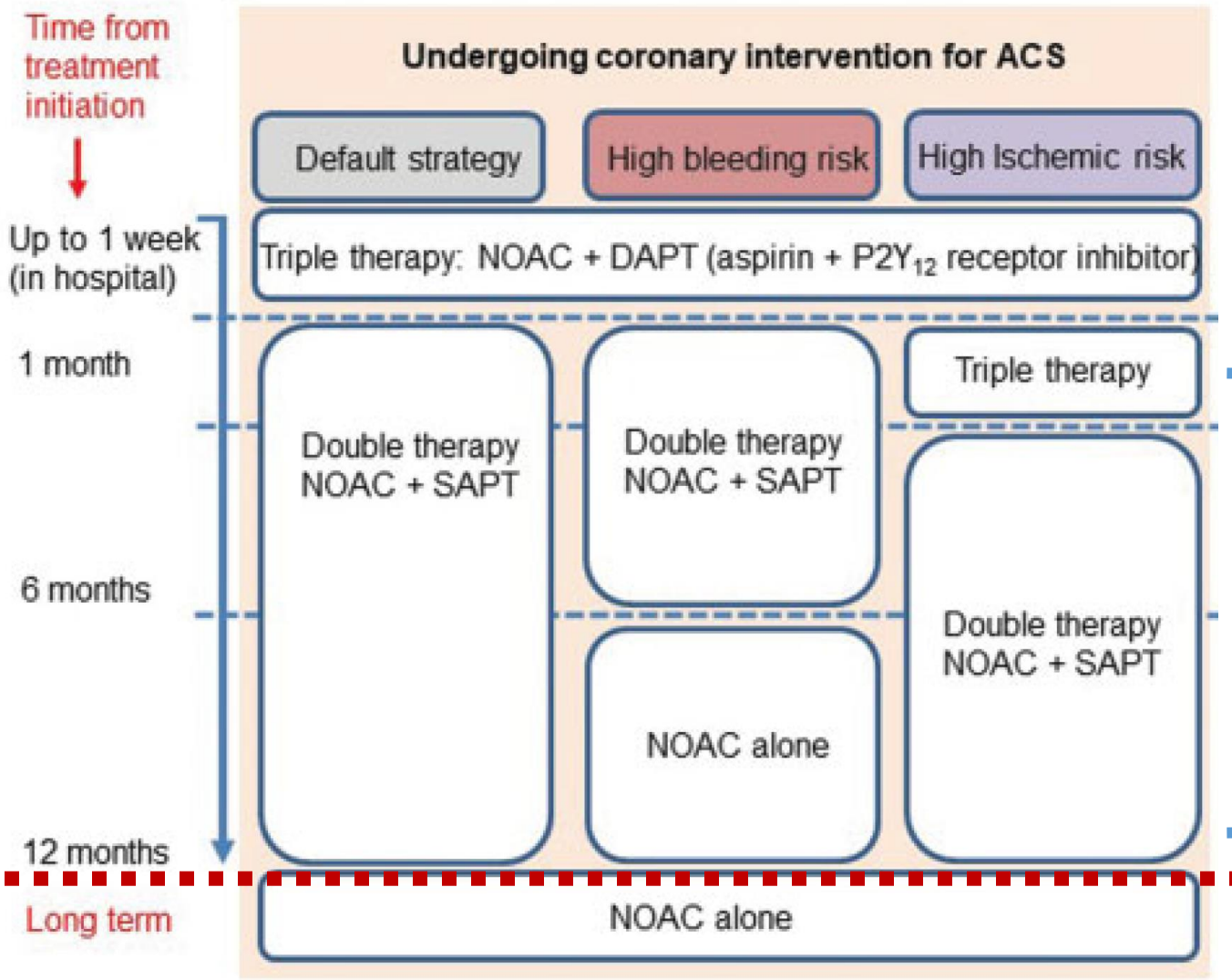
서울아산병원
Asan Medical Center

Disclosure

Investigator initiated trial

* The study was funded by Daiichi-Sankyo (Tokyo, Japan)
and Daewoong Phamaceutical Co., Ltd (Seoul, Korea)

Management of patients requiring OAC undergoing PCI



Triple Rx

Dual Rx

Single Rx -OAC

WOEST,
PIONEER AF-PCI,
RE-DUAL PCI,
AUGUSTUS,
ENTRUST-AF PCI

OAC ALONE
AFIRE
EPIC-CAD

서울아산병원 Asan Medical Center

Eur Heart J 2021;42(14):1289–1367
Hamostaseologie2022;42:73–79

EPIC-CAD trial

the Edoxaban versus Edoxaban with AntiPlatelet Agent in Patients with Atrial Fibrillation and Chronic Stable Coronary Artery Disease

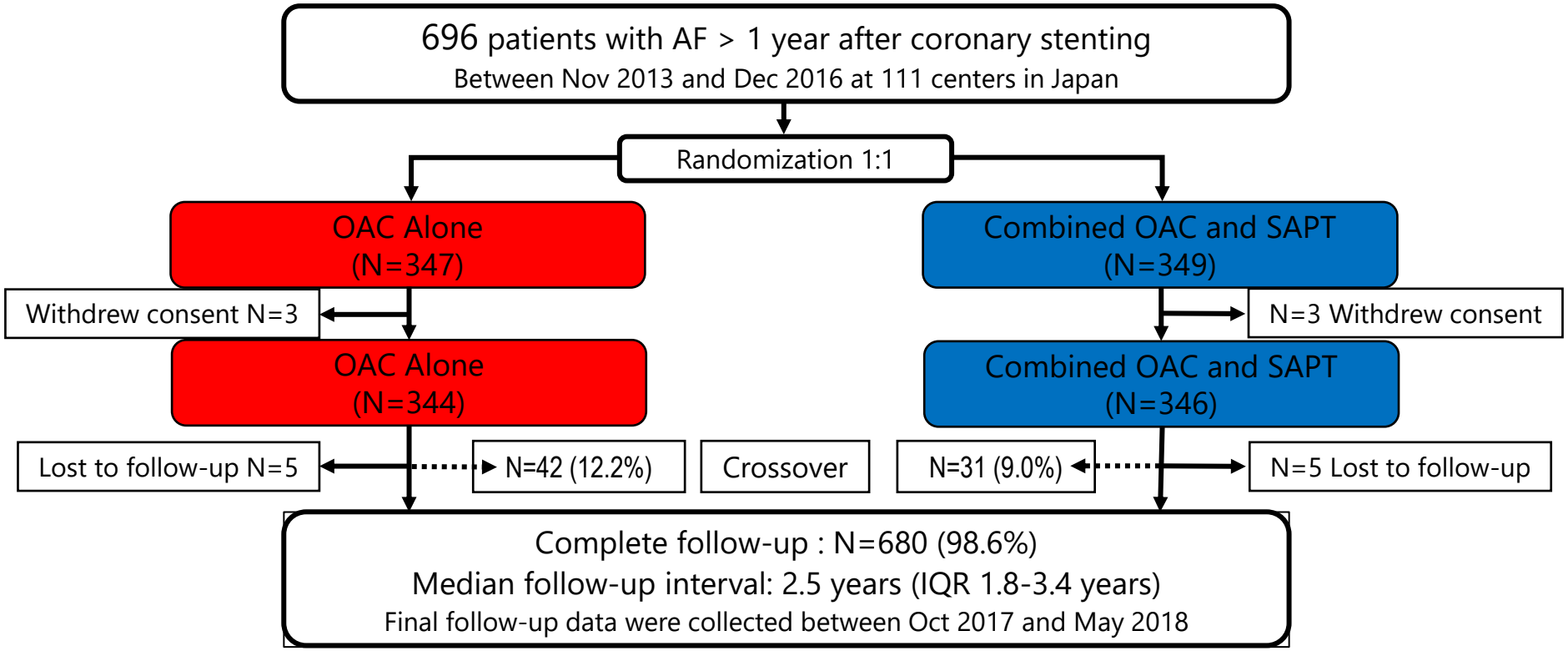
Aims:
To determine whether edoxaban monotherapy (vs. dual edoxaban+SAPT) can reduce the net adverse clinical events compared to combination therapy in AF patients with high thromboembolic risk and stable CAD

Design:
Multicenter, randomized, open-label, superiority trial

OAC-ALONE trial

(Optimizing Antithrombotic Care in Patients With AF and Coronary Stent)

Prospective, multicenter, open-label, noninferiority trial comparing OAC vs OAC+SAPT
Prim. End=death, MI, stroke/SE (analyzed for non-inferiority)
Seonc.End=composite of Prim. End point or ISTH major bleeding



The enrollment was to slow and the study was prematurely terminated before reaching the target population, and the results are inconclusive.

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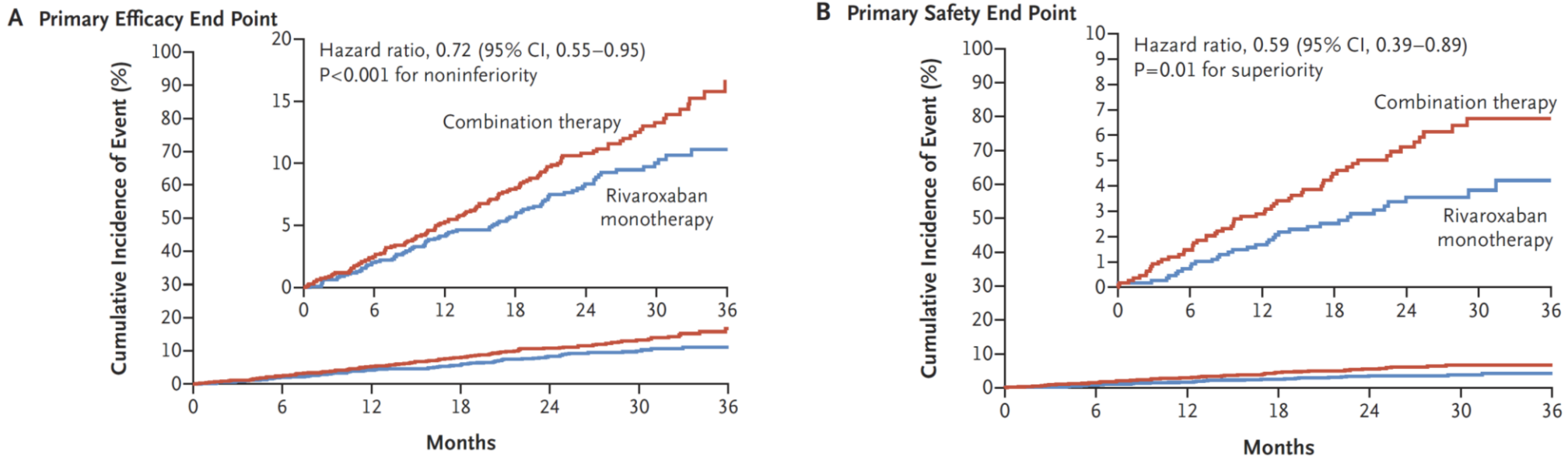
Circulation. 2018;139:604–616

AFIRE

Atrial Fibrillation and Ischemic Events with Rivaroxaban in Patients with Stable CAD

Prospective, multicenter, open-label, trial comparing rivaroxaban vs rivarox+SAPT
Prim. Efficacy End=any death, MI, stroke/SE (non-inferiority)
Prim. Safety End=ISTH major bleeding (superiority)



CONCLUSIONS

As antithrombotic therapy, rivaroxaban monotherapy was noninferior to combination therapy for efficacy and superior for safety in patients with AF and stable CAD.

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N Engl J Med 2019;381:1103-13

Limitations of OAC alone, AFIRE trials

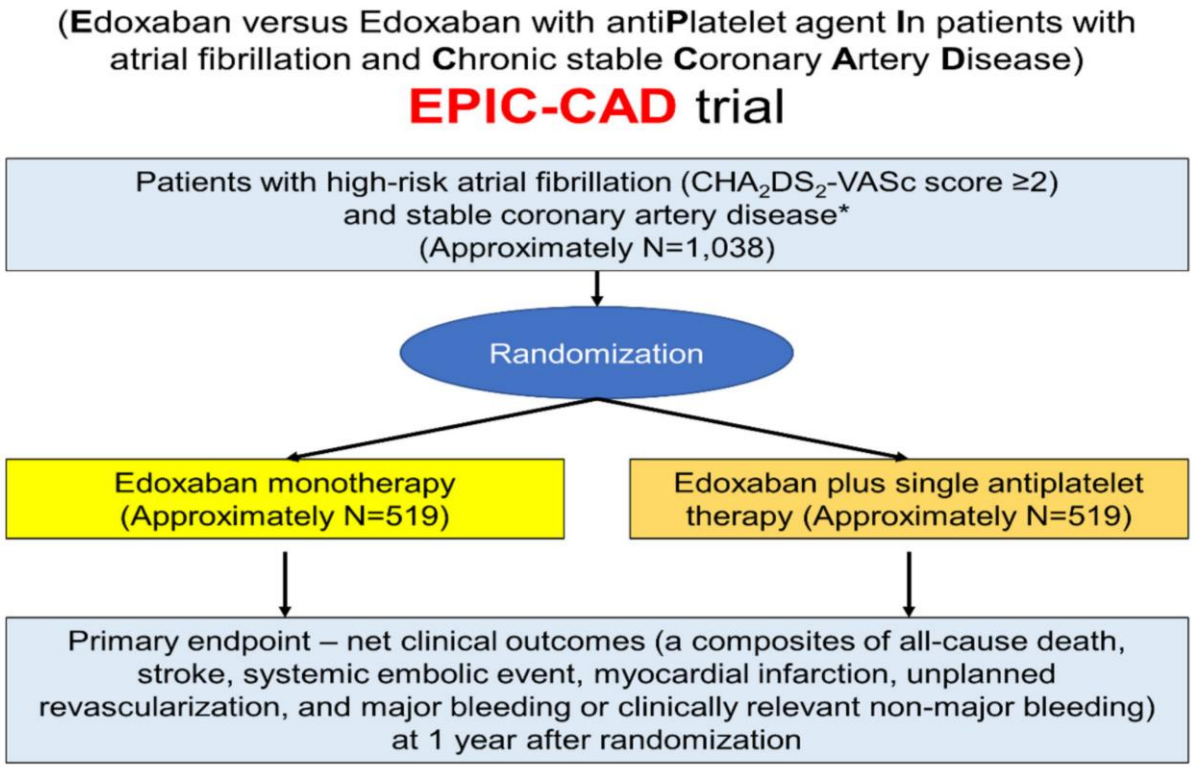
OAC Alone

1. used warfarin (75%) as OAC (DOAC<25%)
2. prematurely terminated and the results, inconclusive

AFIRE

NOAC (Rivaroxaban), but low dose 15/10mg

First to examine the role of "standard" dose NOAC Rx in pts w AF and stable CAD (vs Edox+SAPT)
Sample size - A total of 1040 pts were enrolled from 20 sites in Korea
Primary outcome: a composite of "net" clinical outcomes
(death, stroke/SE, MI, unplanned revascularization, ISTH major bleeding, CRNMB at 1 year
Secondary outcomes: individual components of efficacy and safety outcomes.



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Am Heart J 2022;247:123–131

Study population

>18yrs with both AF and CAD

Key inclusion criteria
- AF w CHA_2DS_2-VASc score ≥2
- stable revascularized CAD (PCI or CABG >6m for stable angina or >1yr for ACS)
- anatomically ≥50% stenosis confirmed by CAG/CTA on OMT not requiring revascularization

Key exclusion criteria
- contraindication to OAC, platelet agents
- history of intracranial bleeding
- mechanical valves, moderate to severe mitral stenosis
- significant hepatic or renal insufficiency

Randomization and treatment group

1:1 ratio to either edoxaban monotherapy or combination therapy
Standard dose edoxaban (60mg or 30mg)

Central randomization was conducted using Interactive Web Response System,
and stratified by the participating center and revascularization status,

Edoxaban 30mg is used in patients with following dose-reduction criteria:

(1) body weight ≤ 60 kg,
(2) moderate-to-severe renal impairment (CrCl 30 and 50-mL/min), or
(3) the concomitant use of P-glycoprotein inhibitors
(cyclosporine, dronedarone, erythromycin, or ketoconazole)

The decision on the type of antiplatelet therapy, either asprin or a P2Y12 inhibitors were made according to the physician's discretion.

EPIC-CAD trial

Time-line

2016
concept

2018
Fund from
Daiich Sankyo

2019.5.14
First patient enrolled

Protocol
Clinicaltrials.com

2022.9
Enrollment
completed

2023.9
1-yr follow-up
completed

Randomization Edoxaban vs Edoxaban plus single antiplatelet

Single antiplatelet group에서 ASA or Clopidogrel의 선택은 연구자 판단에 따라 결정하시면 됩니다.

Visit completion windows & Data Entry

Visit window 안에 대상자들의 follow-up이 이루어질 수 있게 Timely e-CRF 입력을 부탁드립니다.

Adverse Event

FU 중 발생하는 Major Adverse Event는 꼭 e-CRF 해당 event에 같이 입력하여 주세요.

Current rate
99.0%

Enroll
1028

Target
1038

Study NCT03718559
Submitted Date: June 18, 2020 (v9)

Study Identification

Unique Protocol ID:	AMCCVEP2018-01
Brief Title:	Edoxaban Versus Edoxaban With antiPlatelet Agent In Patients With Atrial Fibrillation and Chronic Stable Coronary Artery Disease (EPIC-CAD)
Official Title:	A Multi-centre, Open-labelled, Randomized Controlled Trial Comparing Two Different Anticoagulation Strategies in High-risk Atrial Fibrillation and Stable Coronary Artery Disease
Secondary IDs:	

Study Status

Record Verification:	June 2020
Overall Status:	Recruiting
Study Start:	May 14, 2019
Primary Completion:	December 20, 2021 [Anticipated]
Study Completion:	June 15, 2022 [Anticipated]
First Submitted:	October 23, 2018
First Submitted that Met QC Criteria:	October 23, 2018
First Posted:	October 24, 2018 [Actual]
Last Update Submitted that Met QC Criteria:	June 18, 2020
Last Update Posted:	June 18, 2020 [Actual]

서울아산병원
Asan Medical Center

Summary

1. AF and concomitant CAD is common in clinical practice.
2. Dual therapy (NOAC+SAPT), shown to better in safety compared to warfarin-based Triple therapy in (sub)acute phase of CAD.
3. For pts w stable CAD, NOAC monRx is recommended.
4. EPIC-CAD is a multicenter, randomized, open-label, superiority trial to determine whether edoxaban “monotherapy” can reduce the net adverse clinical events compared to “combination therapy” in AF patients with high thromboembolic risk and stable CAD.