Original Article

Direct Oral Anticoagulants (DOACs)-Based Versus Warfarin-Based Antithrombotic Regimens in Patients with Atrial Fibrillation Underwent Successful Coronary Stenting at Siriraj Hospital

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Objective: To investigate the 1-year bleeding outcome between direct oral anticoagulants (DOACs)-based regimens and warfarin-based regimens in real-world practice in Thai patients with atrial fibrillation (AF) and significant coronary artery disease (CAD).

Materials and Methods: The present study was a retrospective study. The authors reviewed the electronic medical charts of patients treated at the Siriraj Hospital between January 1, 2012 and October 31, 2019. The inclusion criteria were patients with AF and significant CAD that underwent percutaneous coronary intervention (PCI) with a stent and were prescribed or planned to prescribe anticoagulants after the PCI. The primary end point was the International Society on Thrombosis and Hemostasis (ISTH) bleeding during a 1-year follow-up period after successful coronary stenting. The trial assessed for the difference in the bleeding outcome and composite efficacy end point of myocardial infarction, ischemic stroke, and systemic embolism between patients that received warfarin-based regimen and those that received DOACs-based regimen.

Results: The prevalence of patients that received additional oral anticoagulation was 5.1% (679/13,306 patients). One hundred seventy patients met the study inclusion and exclusion criteria. The incidence of the primary end point was 9.0% in the warfarin-based regimen compared with 8.1% in the DOACs-based regimen (p=1.000). The incidence of the composite efficacy end point was 8.3% in the warfarin-based regimen compared with 0% in the DOACs-based regimen (p=0.124).

Conclusion: In patients with AF and significant CAD that underwent PCI, the use of a DOACs-based regimen had no statistically significant difference in bleeding outcome but associated with lower ischemic endpoint. However, due to the limited study sample size, the study had insufficient power to declare the results statistically significant.

Keywords: Coronary artery disease; Atrial fibrillation; DOAC; Warfarin

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In patients with atrial fibrillation (AF) and significant coronary artery disease (CAD) who are undergoing percutaneous coronary intervention (PCI), choosing the best antithrombotic regimen is challenging and it is difficult to balance the thrombotic risk and bleeding risk. Dual antiplatelet therapy (DAPT) with an aspirin plus $P2Y_{12}$ inhibitors is recommended in patients undergoing PCI with stent implantation for reducing the cardiovascular events[1,2], whereas oral anticoagulation is recommended in patients with AF for preventing the stroke risk[3,4]. Recently, there have been many studies into the use of direct oral anticoagulants (DOACs) in patients with AF and significant CAD, such as the PIONEER AF-PCI study[5] in 2016, followed by RE-DUAL PCI[6] in 2017, and AUGUSTUS[7] and ENTRUST-AF PCI[8] in 2019, respectively. These studies reported similar results, namely that antithrombotic regimens with DOACs have a lower bleeding risk compared with triple therapy with warfarin plus DAPT. Recently, the European Society of Cardiology (ESC) produced AF guidelines in 2020 recommend the use of DOAC-

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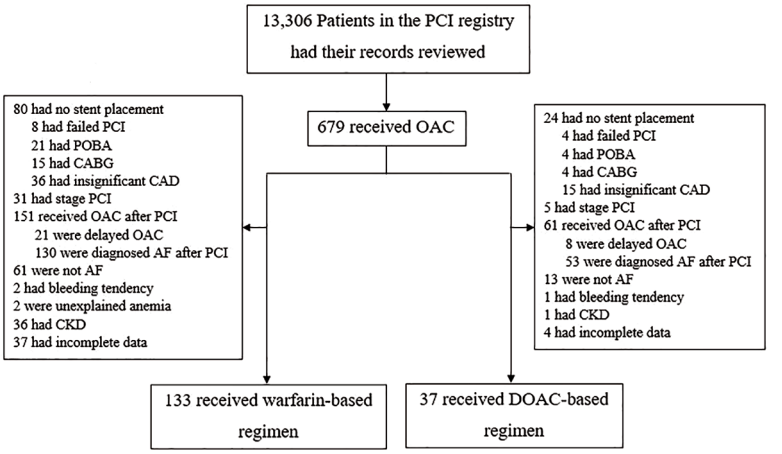

Figure 1. Enrollment of the study participants.

based regimens over warfarin-based regimens[9]. However, there is limited data on the use of DOACs in Thailand and access to such treatment is limited due to their reimbursement status. Consequently, the authors conducted a trial to investigate the 1-year bleeding outcome between the DOAC-based regimens and the warfarin-based regimens in real-world practice in a Thai setting.

Materials and Methods

Study design and patients

The protocol of the present study was approved by the Siriraj Institutional Review Board (SiRB) (COA no. Si 860/2020). The present study was a retrospective cohort study that comprised patients in the PCI registry of Siriraj Hospital treated between January 1, 2012, and October 31, 2019. The present study complied with all the principles in both the Declaration of Helsinki (1964) and all its later amendments. Patients who met all the following criteria were eligible for inclusion, aged at least 18 years old, significant CAD, successfully undergone PCI with a drug-eluting stent (DES) or a bare-metal stent (BMS), history of AF before discharge from the PCI admission, and a planned long-term use of oral anticoagulants. The indication for PCI was ST segment elevation myocardial infarction (STEMI), non-ST segment elevation acute coronary syndrome (NSTE-ACS), or stable CAD. Patients using oral anticoagulants for other conditions such as prosthetic valves, deep vein thrombosis, pulmonary embolism, or left ventricular thrombus, were not eligible and were excluded from the study. Each patient enrolled only one time, the stage PCI on the same patient was not enrolled again. The exclusion criteria were severe renal insufficiency as estimated GFR of 30 mL/minute/1.73 m^2 or less, history of intracranial hemorrhage or severe gastrointestinal bleeding that necessitated a blood transfusion, thrombocytopenia or coagulopathy, and incomplete electronic chart data. Exclusion criteria is shown in Figure 1.

The stroke risk was assessed by the CHA_2DS_2-VASc score, which reflected the risk of stroke in patients with AF not receiving anticoagulants. Scores ranged from 0 to 9, with a higher score indicating higher risk of stroke. Bleeding risk was assessed with the HAS-BLED score, which reflected the risk of bleeding in patients with AF receiving anticoagulants. Scores ranged from 0 to 9, with higher score indicating higher risk of bleeding.

Interventions

The enrolled patients received either a warfarin-based regimen or a DOAC-based regimen based on the primary physician's recommendation. Warfarin-based regimens consisted of warfarin once daily, with dose adjustment to achieve a target of the international normalized ratio (INR) of 2.0 to 3.0, and clopidogrel at a dose of 75 mg once daily, or ticagrelor at a dose of 90 mg twice daily or prasugrel at a dose of 10 mg once daily, with and without low-dose aspirin of 81 mg per day. Patients on DOACs-based regimens received either dabigratan, rivaroxaban, apixaban, or edoxaban plus low-dose aspirin of 81 mg per day and or clopidogrel at a dose of 75 mg once daily, or ticagrelor at a dose of 90 mg twice daily or prasugrel at a dose of 10 mg once daily. The types of DOACs, the combination of antiplatelet, single or dual, and the duration of antiplatelet use depended on the primary physician's recommendation. The data were reviewed

until 1-year after the PCI date.

Outcomes

The primary outcome was the first major or clinically relevant non-major bleeding event, as defined by the International Society on Thrombosis and Hemostatsis (ISTH), in the follow-up period. The secondary outcome was a composite efficacy outcome of thromboembolic events such as myocardial infarction, ischemic stroke, or systemic embolism, and the proportion of DOACs-based regimens in Siriraj Hospital.

Statistical analysis

The present trial was designed to evaluate the hypotheses that DOACs-based regimens is superior to warfarin-based regimen regarding bleeding outcome. Sample size was calculated based on the study from Cannon[6], assuming an event rate for the primary end point of 15.4% in DOACs-based regimens and 26.9% in warfarin-based regimens. The expected ratio of subjects in warfarin-based group to DOACs-based group was 4:1. The authors calculated that including 168 patients on DOAC-based regimens and 672 patients on warfarin-based regimens would give the trial 80% power to detect differences in bleeding outcomes between both antithrombotic regimens.

Categorical data were presented as the frequency and percentage, and continuous variables as the mean ± standard deviation for normally distributed data. Categorical data were compared using the chi-square test or Fisher's exact test, and continuous data were compared using the Student's t-test (normality). A p-value of less than 0.05 was considered statistically significant. All the statistical analyses were performed using PASW Statistics, version 18.0 (SPSS Inc., Chicago, IL, USA).

Results

Between January 1, 2012, and October 31, 2019, 13,306 patients were included in the PCI registry of Siriraj Hospital and their records were reviewed. Among these, 679 patients (5.1%) were diagnosed with AF, but only 170 patients met the inclusion and exclusion criteria. Regarding the patients in each treatment group, 133 patients (78%) received a warfarin-based regimen and 37 patients (22%) received a DOACs-based regimen. The enrollment flowchart is shown in Figure 1.

The baseline characteristics of the patients are shown in Table 1. The mean patient age was 71.8 years old in the warfarin-based regimen group and 73.3 years old in the DOACs-based regimen group. Over 60% of the patients were men. The mean CHA_2DS_2-VASc score was 4.2 in both regimen groups and the mean HAS-BLED scores were 2.2 and 2.1 in the warfarin-based regimen and DOAC-based regimen groups, respectively. Among the patients in both groups, over two-thirds of the patients had stable CAD. Drug-eluting stents were the majority.

Table 2 shows the medications of the patients during discharge. In the warfarin-based regimen group, 132 of the 133 patients (99.2%) received triple antithrombotic therapy during discharge, while only one of the 133 patients (0.8%) received double antithrombotic therapy with warfarin and clopidogrel following the judgement of the primary interventionist. Clopidogrel was the $P2Y_{12}$ inhibitor used in 97.7% of the patients and ticagrelor was used in 2.3%. None of the patients in the present study group received prasugrel. In the DOAC-based regimen group, 30 of the 37 patients (81.1%) received dual antiplatelet therapy. Seven patients in this group were planned to have a delay before taking DOACs during discharge, the longest was delayed for three months. In addition, 23 of the 37 patients (62.2%) received triple antithrombotic therapy and seven (18.9%) received double antithrombotic therapy during discharge. Clopidogrel was the $P2Y_{12}$ inhibitor used in 89.2% of the patients, while ticagrelor was used in 8.1% of DOACs-based antithrombotic therapy group and all of them were among subjects with triple antithrombotic therapy, and prasugrel was used in 2.7% of DOACs-based antithrombotic therapy group and all of them were among subjects with double antithrombotic therapy. Rivaroxaban was the DOAC used in over half of the patients. None of the patients received edoxaban.

At 12 months after PCI, the primary outcome of a major or clinically relevant non-major bleeding event had occurred in 9.0% of patients in the warfarin-based regimen group compared with 8.1% in the DOACs-based regimen group (p=1.000). In the warfarin group, 10 patients had gastrointestinal bleeding, one patient had intracranial bleeding, and one patient had retrobulbar bleeding. In the DOACs group, the three patients with bleeding had gastrointestinal bleeding. The secondary composite outcome occurred only in the warfarin group, where eight of the 133 patients (6.0%) had recurrent myocardial infarction during the 1-year follow-up period and three patients (2.3%) had acute ischemic stroke. No thromboembolic event was noted in the DOACs group. The primary and secondary outcomes are shown in Table 3. The

Table 1. Baseline characteristics of the enrolled patients

	Warfarin-based antithrombotic therapy (n=133); n (%)	DOACs-based antithrombotic therapy (n=37); n (%)	p-value
Age (years); mean±SD	71.8±9.4	73.3±9.1	0.395
Sex			0.564[a]
Male	83 (62.4)	25 (67.6)	
Female	50 (37.6)	12 (32.4)	
Body weight (kg); mean±SD	64.8±11.8	69.2±13.5	0.052
Height (cm); mean±SD	162.1±10.2	163.1±8.0	0.612
Body mass index (kg/cm^2); mean±SD	24.6±3.5	26.0±4.7	0.086
Underlying disease			
Hypertension	118 (88.7)	34 (91.9)	0.766[b]
Diabetes mellitus	52 (39.1)	18 (48.6)	0.296[a]
Dyslipidemia	96 (72.2)	20 (54.1)	0.036[a]
Smoking status			0.049[b]
Never	111 (83.5)	35 (94.6)	
Current smoker	6 (4.5)	2 (5.4)	
Ex-smoker	16 (12.0)	0 (0.0)	
Past history			
Previous heart failure	33 (24.8)	11 (29.7)	0.546[a]
Previous stroke	25 (18.8)	4 (10.8)	0.253[a]
Previous peripheral arterial disease	5 (3.8)	4 (10.8)	0.105[b]
Previous myocardial infarction	46 (34.6)	10 (27.0)	0.387[a]
Previous PCI	46 (34.6)	10 (27.0)	0.387[a]
Previous CABG	15 (11.3)	2 (5.4)	0.370[b]
Previous bleeding	9 (6.8)	2 (5.4)	1.000[b]
CHA_2DS_2-VASc score; mean±SD	4.2±1.7	4.2±1.5	0.928
HAS-BLED score; mean±SD	2.2±0.8	2.1±0.6	0.205
Creatinine (mg/dL); mean±SD	1.2±0.3	1.2±0.3	0.545
Creatinine clearance (mL/minute); mean±SD	60.8±17.1	59.3±21.2	0.666
Type of atrial fibrillation			0.753[a]
Paroxysmal	65 (48.9)	17 (45.9)	
Non-paroxysmal	68 (51.1)	20 (54.1)	
Indications for PCI			0.756[b]
STEMI	5 (3.8)	0 (0.0)	
NSTEMI	38 (28.6)	11 (29.7)	
Stable angina or positive stress test	90 (67.7)	26 (70.3)	
Type of stent			0.071[a]
Drug-eluting	110 (82.7)	35 (94.6)	
Bare-metal	23 (17.3)	2 (5.4)	
Access site			0.043[b]
Radial	28 (21.1)	15 (40.5)	
Femoral	104 (78.2)	22 (59.5)	
Other	1 (0.8)	0 (0.0)	
Mechanical circulatory support			1.000[b]
IABP	3 (2.3)	0 (0.0)	
ECMO	0 (0.0)	0 (0.0)	

SD=standard deviation; DOACs=direct oral anticoagulants; PCI=percutaneous coronary intervention; CABG=coronary artery bypass grafting; IABP=intra-aortic balloon pump counter pulsation; ECMO=extra corporeal membrane oxygenation; NSTEMI=non-ST segment elevation myocardial infarction; STEMI=ST segment elevation myocardial infarction

[a] Chi-square test, [b] Fisher's exact test

Table 2. Medication of the patients during discharge

	Warfarin-based antithrombotic therapy (n=133); n (%)	DOACs-based antithrombotic therapy (n=37); n (%)	p-value
Aspirin	132 (99.2)	30 (81.1)	<0.001[b]
$P2Y_{12}$ inhibitors			0.041[b]
Clopidogrel	130 (97.7)	33 (89.2)	
Ticagrelor	3 (2.3)	3 (8.1)	
Prasugrel	0 (0.0)	1 (2.7)	
Oral anticoagulants			<0.001[b]
Warfarin	133 (100)	0 (0.0)	
Dabigratan	0 (0.0)	11 (29.7)	
Rivaroxaban	0 (0.0)	21 (56.8)	
Apixaban	0 (0.0)	5 (13.5)	
Edoxaban	0 (0.0)	0 (0.0)	
ACEIs or ARBs	75 (56.4)	23 (62.2)	0.530[a]
Beta-blockers	109 (82.0)	29 (78.4)	0.623[a]
Statins	121 (91.0)	33 (89.2)	0.753[b]
PPIs	102 (76.7)	27 (73.0)	0.640[a]

DOACs=direct oral anticoagulants; ACEIs=angiotensin-converting enzyme inhibitors; ARBs=angiotensin receptor blockers; PPIs=proton pump inhibitors

[a] Chi-square test, [b] Fisher's exact test

Table 3. Primary and secondary outcomes

	Warfarin-based antithrombotic therapy (n=133); n (%)	DOACs-based antithrombotic therapy (n=37); n (%)	p-value
ISTH bleeding	12 (9.0)	3 (8.1)	1.000[b]
Composite efficacy outcome	11 (8.3)	0 (0.0)	0.124[b]
Myocardial infarction	8 (6.0)	0 (0.0)	
Ischemic stroke	3 (2.3)	0 (0.0)	
Systemic embolism	0 (0.0)	0 (0.0)	

DOACs=direct oral anticoagulants; ISTH=international society on thrombosis and hemostasis

[b] Fisher's exact test

comparison of proportions of DOACs among all subjects underwent PCI who required OAC in each year are shown in Figure 2.

Discussion

In the present study, the prevalence of patients with significant CAD with AF who had undergone PCI and received oral anticoagulation was 5.1% (679/13,306 patients). The incidence of ISTH bleeding during 1-year follow-up was not statistically significantly different between the two groups

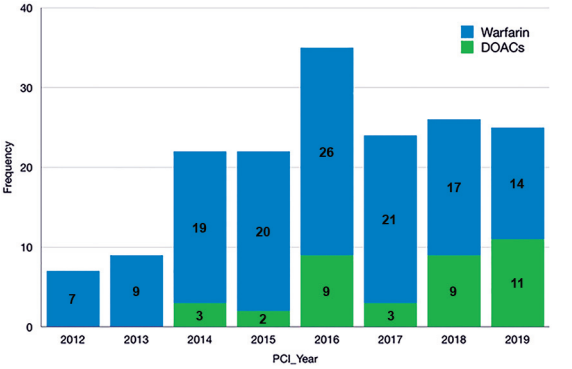

Figure 2. Number of subjects taking anticoagulants in Siriraj PCI registry.

with 9.0% in the warfarin-based regimen group versus 8.1% in the DOACs-based regimen group. The incidence of the composite efficacy endpoint of thromboembolic events such as myocardial infarction, ischemic stroke, or systemic embolism, tended to be higher in the warfarin-based regimen group, but not statistically significant at 8.3% in the warfarin-based regimen group versus 0% in the DOACs-based regimen group. However, the data should be interpreted with caution due to the lack of sufficient power from limited sample of patients.

The incidence of the primary outcome in the present study was lower than in the AF-PCI trial. The rate of the primary outcome in the warfarin-based regimen in the present study, which was 9.0%, with that in the warfarin-based triple therapy group in the RE-DUAL PCI study, which was 26.9%, and that in the DOAC-based regimen in the present study, which was 8.1%, with that in the 110 mg dabigatran dual therapy group, which was 15.4%, and that in the 150 mg dabigatran dual therapy group, which was 20.2% in the RE-DUAL PCI study[6]. This may be associated with the lower HAS-BLED scores of the participants in the present study than in the previous studies as HAS-BLED score of 2.1 to 2.1 versus 2.6 to 2.8 in the REDUAL-PCI, or 2.8 to 2.9 in the AUGUSTUS study[6,7].

The composite outcome of thromboembolic events occurred more often in the warfarin-based regimen group than in the DOACs-based regimen group at 8.3% versus 0% (p=0.124), but not statistically significant. A higher incidence of previous stroke, previous myocardial infarction, and a higher CHA_2DS_2-VASc score may be associated with the higher incidence of ischemic stroke and myocardial infarction than in the previous AF-PCI trial. One-third of the patients presented with NSTEMI. In-hospital

MACE occurred 5.6% in these patients[10]. It should also be noted that the warfarin-based regimen group had a higher incidence of life-threatening bleeding, such as intracranial bleeding and retrobulbar bleeding, which could require a longer duration of antiplatelet therapy and anticoagulation cessation. The complex PCI was accounted for 50% in the authors' institution. Consistency of anticoagulation is important in the patient with high bleeding and high thrombotic risk when antiplatelet was planned to be shortened or omitted. Prevalence of aspirin resistance and high on-clopidogrel treatment platelet reactivity was 21.6% and 38.7%, respectively, in Thai patients[11,12]. In real world setting when encounter more complexity of procedures, anticoagulation regimen with consistent anticoagulation level would provide benefit in thromboembolic endpoint. Further study with adequate sample size would provide answer in these patients.

The present study cohort comprised patients from 2012 to 2019, but the studies from the AF-PCI trials were published in 2016 to 2019, so there were no definite regimens for DOACs until recently. This may explain the difference in recommending DOAC-based regimens among the primary physicians. In patients who underwent PCI and required oral anticoagulation, the DOACs that could be used with antiplatelets were mentioned in the 2016 ESC Guidelines for the management of AF[13] and then became a class IIa recommendation in the 2017 ESC focused update on dual antiplatelet therapy in CAD[14]. Finally, the use of DOACs was recommended over warfarin in patients with AF and with an indication for concomitant antiplatelet therapy in the 2020 ESC Guidelines for the diagnosis and management of AF[9] and definite DOAC regimens were then described.

This present trial has several limitations to note. First, the study was designed as a retrospective medical chart review, unlike the other AF-PCI trials that were designed as multicenter, randomized studies. The baseline characteristics between the two participant groups in the present study were not equal and some data were incomplete, which depended on the records of the primary physician. Second, the present study was conducted in a single center, and so it may not reflect the overall Thai population. Third, the sample size was small, and the trial was not powered sufficiently to establish the outcomes. Assuming an 80% power to detect difference between the treatment groups at an alpha level 0.05, the total sample size needed to be 840 participants. However, despite considering all the patients enrolled in the last eight years in the PCI registry in Siriraj Hospital, only 170 patients met the inclusion and exclusion criteria. The use of multicenter data could resolve this problem.

In summary, the authors found that among the AF patients with significant CAD that underwent PCI, the use of a DOACs-based regimen had no statistically significant difference in bleeding outcome but associated with lower ischemic endpoint. However, due to the limited study sample size, the present study had insufficient power to declare the results statistically significant.

What is already known on this topic?

In patients with AF and significant CAD undergoing PCI, choosing the best antithrombotic regimens is challenging. It is difficult to balance the thrombotic risk and the bleeding risk. Recently, the ESC AF guidelines 2020 recommended the use of a direct oral anticoagulant DOACs-based regimens over the warfarin-based regimens. However, there is limited data on the use of DOACs in Thailand and the access to such treatment is limited due to their reimbursement status.

What this study adds?

The prevalence of patients with significant CAD with AF that underwent PCI and received oral anticoagulation was 5.1%. DOACs-based regimen had no statistically significant difference in the incidence of the ISTH bleeding outcome, but associated with lower thromboembolic events such as myocardial infarction, ischemic stroke, or systemic embolism, during 1-year follow-up. However, due to the limited study sample size, the study had insufficient power to declare the results statistically significant.

Conflicts of interest

All the authors declare they have no personal or professional conflicts of interest and received no financial support from the companies that produce or distribute the drugs, devices, or materials described in the present report.

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