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DAPT score in stenting for atrial fibrillation

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Abstract

Background: The DAPT score identifies patients with expected benefit from extended dual antiplatelet therapy beyond 1 year after percutaneous coronary intervention (PCI). In a post-hoc analysis from the AFCAS registry, we explored the value of DAPT score to predict outcome in patients with atrial fibrillation (AF) undergoing PCI.

Methods and results: Outcome measures included major adverse cardiac/cerebrovascular events (MACCE) [all-cause death, myocardial infarction, repeat revascularization, stent thrombosis, or stroke/transient ischemic attack] and bleeding events. At 12-month follow-up, patients with a DAPT score ≥1 had a higher incidence of MACCE, all-cause death, myocardial infarction (p=0.004, p=0.006, and p=0.013, respectively), but a similar bleeding rate (p=0.66), versus those with a DAPT score <1. In a subgroup of patients at high risk of stroke who received triple therapy for 1 month only, DAPT score ≥1 was associated with a higher incidence of MACCE, all-cause death, myocardial infarction (p=0.002, p=0.015, and p=0.039, respectively), but a similar bleeding rate (p=0.81).

Conclusions: In AF patients undergoing PCI, a DAPT score ≥1 was associated with a higher incidence of thrombotic events, and a similar incidence of bleeding events compared with a DAPT score <1. These results were consistent in patients at high risk of stroke who received triple therapy for 1 month.

Introduction

Atrial fibrillation (AF) is the most common sustained arrhythmia with a prevalence of 1-2% in the European Union [1]. Coronary artery disease has been reported in 34% of patients with AF; and 21% need revascularization [2]. The optimal management of antithrombotic therapy in patients with AF who undergo percutaneous coronary intervention (PCI) is unknown. The European Society of Cardiology guidelines on the management of AF recommend that patients with AF who have ≥1 additional stroke risk factor who undergo elective PCI and stenting should receive triple therapy [oral anticoagulation (OAC), clopidogrel, and aspirin] for a short period, followed by a period of dual therapy (OAC plus a single antiplatelet) [3].

These patients frequently have thrombotic and bleeding events shortly after index procedure [4], and thus, there is an unmet clinical need for better risk prediction tools to identify who would benefit from longer versus shorter antiplatelet therapy in addition to OAC. The performance of bleeding risk prediction scores HAS-BLED, ATRIA, mOBRI and REACH was poor in detecting major bleeds in patients with AF undergoing PCI [5].

The DAPT (Dual Antiplatelet Therapy) score is a clinical prediction rule based on ischemic and bleeding risk factors that helps discriminate patients with greater expected benefit versus those with greater expected harm from extended dual antiplatelet therapy beyond 1 year, among those who underwent coronary stenting, had no major ischemic or bleeding event within the first year, and were not receiving OAC [6].

In this post-hoc analysis from the AFCAS registry, we explored the value of the DAPT score to predict thrombotic and bleeding events in patients with AF undergoing PCI.

Methods

Patient selection and study design

The AFCAS (management of patients with Atrial Fibrillation undergoing Coronary Artery Stenting) registry is a prospective multi-center observational study that enrolled consecutive patients with AF who underwent PCI and stenting [4]. The inclusion criterion was ongoing/history of AF (paroxysmal, persistent, or permanent). The only exclusion criteria were unwillingness/inability to participate in the study or to give informed consent. In each participating center, PCI was performed according to local practice, and patients were followed up for 12 months. Peri-procedural and post-procedural antithrombotic regimens were at operator's discretion. Follow-up was performed by telephone calls/clinic visits scheduled at 1, 3, 6, and 12 months after PCI. Patients were enquired about clinical outcome endpoints (described below), hospitalization, and medications. CHA_2DS_2-VASc and HAS-BLED scores were calculated to evaluate the individual risks for stroke and bleeding events, respectively. The DAPT score was calculated as previously described [6]. Briefly, the scoring system assigned 1 point each for myocardial infarction (MI) at presentation, prior MI or PCI, diabetes, stent diameter less than 3 mm, smoking, and paclitaxel-eluting stent; 2 points each for history of congestive heart failure/low ejection fraction and vein graft intervention; −1 point for age 65 to younger than 75 years; and −2 points for age 75 years or older.

Ethical standards

This investigator-driven study was conducted according to the guidelines of the 1964 Declaration of Helsinki. The study protocol was approved by the ethics committees of the

participating centers. Informed written consent was obtained from every patient after full explanation of the study protocol. The AFCAS registry is registered with ClinicalTrials.gov under the identifier: NCT00596570.

Study definitions and endpoints

The primary outcome measures were: 1) major adverse cardiac/cerebrovascular events (MACCE), and 2) bleeding events during 12 months follow-up. The composite endpoint of MACCE was defined as the first occurrence of all-cause death, MI, repeat revascularization, stent thrombosis, or stroke/transient ischemic attack. MI was defined according to the Third Universal Definition [7]. Repeat revascularization was defined as PCI or coronary bypass surgery to treat significant stenosis (>50%) in the previously treated vessel. Stent thrombosis was adjudicated according to the criteria of definite or probable stent thrombosis described by the Academic Research Consortium [8]. Transient ischemic attack was defined as a transient (<24 hours) focal neurological deficit adjudicated by neurologist, whereas stroke was defined as a permanent focal neurological deficit adjudicated by neurologist and confirmed by computed tomography/magnetic resonance imaging. Bleeding events were defined according to the Bleeding Academic Research Consortium (BARC) criteria, and included events adjudicated as minor (BARC 2), and major (BARC 3a, 3b, 3c, and 5) [9].

Statistical analysis

Continuous variables were reported as the mean ± standard deviation. Categorical variables were described with absolute and relative (percentage) frequencies. Comparisons were performed using the unpaired 2-tailed *t*-test for continuous variables, and the Pearson chi-square test or Fisher Exact test for categorical variables, as appropriate. The calibration of the DAPT score as a continuous variable in predicting 12-month ~~mortality and~~ MACCE was

assessed using the Hosmer-Lemeshow "goodness-of-fit" test, estimating the calibration slope and assessing the calibration plot, while its discrimination ability was assessed using the receiver operating characteristic curve. MACCE at 12 months was considered as a binary endpoint since follow-up at 12 months was completed in all patients and no competing risk existed. The area under the curve (AUC) with 95% confidence interval (CI) was reported. The Youden's test was used to identify the best cutoff value of the DAPT score in predicting 12-month MACCE. This cutoff value was used to dichotomize the DAPT score. Statistical analyses were performed using SPSS software, version 20 (IBM SPSS Inc., Chicago, IL, USA) and easyROC software (http://www.biosoft.hacettepe.edu.tr/easyROC/).

Results

Baseline characteristics

For the current analysis, we included 929 consecutive patients with AF who underwent PCI between October 2008 and August 2010 at 17 institutions, in 5 European countries. Mean age was 73.0 ± 7.9 years, 276 (29.7%) were females, 460 (49.5%) had permanent AF, 528 (56.8%) were already receiving vitamin K antagonist (VKA) upon enrolment, 529 (56.9%) presented with acute coronary syndrome, 915 (98.5%) were at high risk of stroke (CHA_2DS_2-VASc score >1), 709 (76.3%) were at high pre-estimated risk of bleeding (HAS-BLED score ≥3). Mean peri-procedural International Normalized Ratio was 1.9 ± 0.7.

The DAPT score showed a modest discriminatory ability and good calibration in predicting 12-month MACCE (AUC 0.566, 95%CI 0.522-0.611, Hosmer-Lemeshow test: p=0.698, calibration slope: 0.966, Fig. ???). ~~and mortality (AUC 0.592, 95%CI 0.534-0.649, Hosmer-Lemeshow test: p=0.748).~~

Youden's test showed that the best cutoff of the DAPT score in predicting MACCE was 1 (sensitivity: 61.7%, specificity 50.2%, negative predictive value 82.5%, positive predictive value 25.6%). Further analyses were then performed using this cutoff value.

In the whole cohort, the DAPT score showed normal distribution, with 445 (47.9%) patients having score <1. Patients with a DAPT score ≥1 were less often at high risk of stroke (p=0.046), and less often at high risk of bleeding, versus those with a DAPT score <1 (p<0.001) (Supplementary Table 1). At 12-month follow-up, patients with a DAPT score ≥1 had a higher incidence of overall MACCE, all-cause death, and MI (p=0.004, p=0.006, and p=0.013, respectively), but a similar rate of BARC 2-5 bleeding (p=0.66) compared with those with a DAPT score <1 (Table 1).

Among the whole cohort, 78 (8.4%) had access site complications. In 851 patients without access site complications, the DAPT score also showed normal distribution, with 406 (47.7%) patients having score <1. In this subgroup of patients, those with a DAPT score ≥1 had a higher risk of stroke (p=0.03), and lower risk of bleeding (p<0.001) compared with those with a DAPT score <1 (Supplementary Table 2). At 12-month follow-up, patients with a DAPT score ≥1 had a higher incidence of overall MACCE (p=0.002), all-cause death (p=0.004), and MI (p=0.005), but a similar rate of BARC 2-5 bleeding (p=0.25) compared with those with DAPT score <1 (Table 2).

Among 851 patients without access site complications, 307 (36.1%) patients received triple therapy (VKA, clopidogrel, and aspirin) for 1 month only. In these 307 patients, the DAPT score again showed normal distribution, with 167 (54.4%) patients having score <1. Moreover, in these patients, those with a DAPT score ≥1 were less often at high risk of bleeding (p=0.001), but had a similar risk of stroke (p=1.0) compared with those with a DAPT score <1 (Supplementary Table 3). Among these 307 patients, only 2 (0.7%) were at low risk

of stroke. We analyzed the clinical outcome stratified by the DAPT score ≥1 in 305 patients without access site complications who received triple therapy for 1 month only and were at high risk of stroke. The prescribed duration of antithrombotic medications stratified by a DAPT score ≥1 was comparable in this selected subgroup (Table 3). At 12-month follow-up, patients with a DAPT score ≥1 (n=139) had a higher incidence of overall MACCE, all-cause death, and MI (p=0.002, p=0.015, and p=0.039, respectively), a trend to more frequent revascularization events (p=0.054), but a similar rate of BARC 2-5 bleeding (p=0.81), versus those with a DAPT score <1 (n=166) (Table 4). Since the higher incidence of overall MACCE in these patients was driven by higher rates of all-cause death and MI, we explored the time of occurrence of these events in relation to the first 1 month (triple therapy). In all 305 patients, 83.3% (25 out of 30 events) of all-cause death events occurred after the first 1 month (75% in patients with DAPT score ≥1 versus 100% in patients with DAPT score <1, p=0.14); and 84.2% (16 out of 19 events) of MI events occurred after the first 1 month (84.6% in patients with a DAPT score ≥1 versus 83.3% in patients with DAPT score <1, p=1.0).

Discussion

Major findings

In the current post-hoc analysis from the AFCAS registry, a DAPT score ≥1 compared with a score <1, was associated with a higher incidence of coronary thrombotic events, and a similar incidence of bleeding events.

Our results were consistent in patients without access site complications. In a selected subgroup of patients without access site complications who were at high risk of stroke and received triple therapy for 1 month only, a DAPT score ≥1 compared with a score <1, was again associated with a higher incidence of coronary thrombotic events, with a similar incidence of bleeding events; most coronary thrombotic events occurred after the first

month. A DAPT score ≥1 had modest accuracy to predict thrombotic and bleeding events at 12-month follow-up.

Antithrombotic regimen after coronary stenting in patients with AF

There is some controversy on the optimal antithrombotic regimen in patients with AF who need lifelong oral anticoagulation, and undergo PCI or develop acute coronary syndrome. Most of the available data derive from small single-center retrospective cohorts or subgroup analysis of randomized trials [3]. Unfortunately, there are no adequately powered randomized trials that compare efficacy and safety for alternative antithrombotic regimens in patients with AF who undergo PCI or develop acute coronary syndrome. Unanswered questions include change of antithrombotic regimen over time, and the duration of each antithrombotic medication. The current European Society of Cardiology guidelines on the management of AF recommend that patients with AF at risk of stroke who undergo PCI or develop acute coronary syndrome should receive a short period of triple therapy (OAC, clopidogrel, and aspirin), followed by a period of dual therapy (OAC plus a single antiplatelet) [3]. In patients who undergo PCI, triple therapy should be considered for 1 month (Class IIa, Level of Evidence B), followed by dual therapy; the duration of dual therapy being based on the bleeding risk: in those at low risk of bleeding, dual therapy should be considered till the end of 12 months; in those at high risk of bleeding, dual therapy should be considered till the end of 6 months (Class IIa, Level of Evidence C) [3]. In patients who develop acute coronary syndrome, triple therapy should be considered (Class IIa, Level of Evidence B), followed by dual therapy; the duration of triple therapy is based on the bleeding risk: in those at low risk of bleeding, triple therapy should be considered for 6 months; in those at high risk of bleeding, triple therapy should be considered for 1 month; in either case, dual therapy should be considered till the end of 12 months (Class IIa, Level of

Evidence C) [3]. In either case, antithrombotic regimen continued after 1 month was based on assessment of the individual bleeding risk.

The weak Level of Evidence for recommending continued antithrombotic regimen after the first month reflects insufficiency of the available data. These recommendations are largely based on expert opinion, or extrapolation of data from observational studies, subgroup analysis, and one small randomized trial [10-13].

Calculation of the HAS-BLED score has some limitations for everyday clinical use: e.g. confirming 'Labile International Normalized Ratio' (defined by 'time in therapeutic range' <60%) is not always feasible. The definition of abnormal liver or renal function needs specific laboratory measurements, and confirmation of alcohol usage history is often challenging. HAS-BLED as well as ATRIA, REACH, and mOBRI scores failed to predict bleeds in an earlier report from AFCAS registry [5], although HAS-BLED score did predict bleeding in another cohort of ACS [14].

In the current study, we employed the DAPT score – a newly introduced clinical risk prediction rule based on a constellation of both ischemic and bleeding risk factors – to identify patients at higher 12-month thrombotic risk among those with AF in need for OAC (CHA_2DS_2-VASc score >1) who underwent PCI with stenting (nearly 60% acute coronary syndrome) and already received triple therapy for 1 month. In this way, we explored whether the score meant for long-term risk assessment in an intermediate-risk patient cohort is valid for mid-term risk assessment in a high-risk cohort. We found that in these patients, a DAPT score ≥1 was associated with a higher incidence of coronary thrombotic events (death and MI), but with a similar incidence of bleeding events. Moreover, around 80% of the coronary thrombotic events occurred after the first month. We opted to exclude patients who developed access site complications since in these, the consequent

antithrombotic regimen and the event rates might have been influenced by access site events, introducing selection bias. Given the comparable rates of bleeding events and the largely comparable distribution of the duration of prescribed antithrombotic medications between the 2 groups (Tables 3 and 4), there is some reason to suggest that those patients who had a DAPT score ≥1 may benefit from triple therapy extended beyond 1 month. This entails extending the duration of antiplatelet medications (mainly clopidogrel), given that the virtually all patients with a DAPT score ≥1 were prescribed lifelong VKA (Table 3). This could be viewed in light of the clinical presentation of the AFCAS cohort; nearly 60% presented with acute coronary syndrome: in these patients, extending the duration of triple therapy to 6 months – rather than 1 month – may be based on risk stratification for thrombotic and bleeding events by a DAPT score ≥1, instead of risk stratification for bleeding events by HAS-BLED score <3. Similar consideration might be held for patients undergoing PCI for stable angina. It should be noted that nearly one-fourth of the AFCAS cohort received drug-eluting stents; these were mostly first-generation devices at the time of patient enrolment in the AFCAS registry. Patients who received these devices needed extended duration of dual antiplatelet therapy, mainly clopidogrel. An important advantage of the DAPT score is that it accounts for the risk of bleeding. In the current report, patients with a DAPT score ≥1 were less often at high risk of bleeding (HAS-BLED score ≥3), and had comparable rates of bleeding events, versus those with a DAPT score <1. In such patients, extending the duration of triple therapy beyond 1 month might not increase the incidence of bleeding events. However, this hypothesis needs to be confirmed in adequately powered randomized trials.

Limitations

The current study has all the inherent limitations of observational study design, including individual decision-making in treatment choice. This may introduce selection bias, even though the antithrombotic medications prescribed at discharge were comparable between the 2 subgroups. Another limitation is the heterogeneity of cohort among the participating centers, and some variations in peri-procedural routines. The statistical power of the current analysis is limited by the absolute low rates of stent thrombosis and stroke, and the relatively small sample size; therefore, lack of significant difference between comparison groups might be due to type II statistical error. Sample size requirement for external model validation requires at least 100 events in the validation dataset for reliable calculation of performance indices. For some outcome events, the number of events was lower than 100, therefore external validation for these outcome events might be less reliable. Moreover, although the DAPT score predicted coronary thrombotic events in a selected cohort, it was insufficient for prediction of bleeding events. The strength of the registry is enrolment of consecutive patients with the only exclusion criterion being unwillingness/inability to participate in the study. In this sense the registry cohort represents well real-world patients with AF referred for PCI.

Conclusion

In patients with AF who undergo PCI, the DAPT score showed modest discrimination and good calibration. However, a DAPT score ≥1 was associated with a higher incidence of coronary thrombotic events, and a similar incidence of bleeding events compared with DAPT score <1. These findings were consistent in a selected subgroup without access site complications who were at high risk of stroke and received triple therapy for 1 month only. Most coronary thrombotic events occurred after the first month.

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Conflicts of interest: none

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Figure ???. Calibration plot of the DAPT score in predicting 12-month MACCE

Table 1 Clinical outcome of the 2 groups stratified by DAPT score ≥1 in the whole cohort (n=929)

	DAPT score ≥1 (N=484)	DAPT score <1 (N=445)	*P* Value
MACCE	124 (25.6)	79 (17.8)	0.004
All-cause mortality	68 (14.0)	37 (8.3)	0.006
Myocardial infarction	37 (7.6)	17 (3.8)	0.013
All revascularizations	44 (9.1)	29 (6.5)	0.14
Stent thrombosis	8 (1.7)	7 (1.6)	0.92
Stroke/arterial embolism	11 (2.3)	12 (2.7)	0.68
BARC 2-5 Bleeding	85 (17.6)	83 (18.7)	0.66

Variables are presented as frequency (percentage).

BARC indicates Bleeding Academic Research Consortium; MACCE, major adverse cardiac and cerebrovascular events.

Table 2 Clinical outcome of the 2 groups stratified by DAPT score ≥1 in patients without access site complications (n=851)

	DAPT score ≥1 (N=445)	DAPT score <1 (N=406)	*P* Value
MACCE	114 (25.6)	68 (16.7)	0.002
All-cause mortality	63 (14.2)	32 (7.9)	0.004
Myocardial infarction	34 (7.6)	13 (3.2)	0.005
All revascularizations	40 (9.0)	25 (6.2)	0.12
Stent thrombosis	7 (1.6)	5 (1.2)	0.67
Stroke/arterial embolism	10 (2.3)	10 (2.5)	0.84
BARC 2-5 Bleeding	51 (11.5)	57 (14.0)	0.25

Variables are presented as frequency (percentage).

BARC indicates Bleeding Academic Research Consortium; MACCE, major adverse cardiac and cerebrovascular events.

Table 3 Prescribed duration of antithrombotic treatments at discharge in the 2 groups stratified by DAPT score ≥1 in patients without access site complications who were at high risk of stroke and received triple therapy for 1 month (n=305)

	DAPT score ≥1 (N=139)	DAPT score <1 (N=166)
Prescribed aspirin duration		
Lifelong	81 (59.7)	95 (57.2)
12 months	7 (5.0)	14 (8.4)
6 months	2 (1.4)	4 (2.4)
3 months	1 (0.7)	5 (3.0)
1 months	46 (33.1)	48 (28.9)
Prescribed clopidogrel duration		
12 months	11 (7.9)	15 (9.0)
9 months	1 (0.7)	0 (0)
6 months	1 (0.7)	1 (0.6)
3 months	2 (1.4)	9 (5.4)
1 months	124 (89.2)	141 (84.9)
Prescribed VKA duration (n=245)		
Lifelong*	98 (99.0)	142 (97.3)
3 months*	0 (0)	1 (0.7)
1 months*	1 (1.0)	3 (2.1)

Continuous variables are presented as mean ± standard deviation, whereas categorical variables are presented as frequency (percentage).

*The number of patients is 99 for patients with DAPT score ≥1, versus 146 for patients with DAPT score <1

VKA indicates vitamin K antagonist.

Table 4 Clinical outcome of the 2 groups stratified by DAPT score ≥1 in patients without access site complications who were at high risk of stroke and received triple therapy for 1 month (n=305)

	DAPT score ≥1 (N=139)	DAPT score <1 (N=166)	*P* Value
MACCE	40 (28.8)	24 (14.5)	0.002
All-cause mortality	20 (14.4)	10 (6.0)	0.015
Myocardial infarction	13 (9.4)	6 (3.6)	0.039
All revascularizations	16 (11.5)	9 (5.4)	0.054
Stent thrombosis	3 (2.2)	2 (1.2)	0.66
Stroke/arterial embolism	4 (2.9)	3 (1.8)	0.70
BARC 2-5 Bleeding	18 (12.9)	20 (12.0)	0.81

Variables are presented as frequency (percentage).

BARC indicates Bleeding Academic Research Consortium; MACCE, major adverse cardiac and cerebrovascular events.