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Prognostic Value of the PARIS Thrombotic Risk Score for 2-Year Mortality After Percutaneous Coronary Intervention

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Abstract

The Patterns of non-Adherence to Anti-Platelet Regimen in Stented Patients (PARIS) thrombotic risk score is a novel score for predicting the risk of coronary thrombotic events after percutaneous coronary intervention (PCI). We assessed the prognostic value of this score for mortality in patients with PCI. In this prospective, observational study, we enrolled 10 724 consecutive patients underwent PCI. The primary end point was all-cause death and the secondary end point was major adverse cardiovascular and cerebrovascular events (MACCE) as a composite of all-cause death, myocardial infarction, revascularization, stent thrombosis, or stroke. Among 9782 patients without in-hospital events, a total of 97 deaths and 1002 MACCE occurred during the 2-year follow-up. The mortality risk of patients in the high-risk group was 2.31 times higher than that in the low-risk group (hazard ratio, 2.31; $P = .001$). This risk score showed prognostic value in evaluating mortality (area under the receiver operating characteristic curve [AUROC], 0.607; 95% confidence interval [CI], 0.551-0.663) and MACCE (AUROC, 0.544; 95% CI, 0.526-0.563; both $P < .001$). The prognostic value of mortality was higher than that of MACCE ($Z = 2.09$, $P = .04$). The PARIS thrombotic risk score shows modest prognostic value for mortality and MACCE, and the prognostic value of mortality is better than that of MACCE.

Keywords

percutaneous coronary intervention, prognosis, death, major adverse cardiovascular and cerebrovascular events

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Introduction

Percutaneous coronary intervention (PCI) is a well-established treatment for patients with coronary artery disease and evidence of myocardial ischemia. The number of PCIs is increasing every year. Dual-antiplatelet therapy (DAPT) of aspirin plus a P2Y12 inhibitor is a standard treatment for patients undergoing PCI or stent implantation and can reduce thrombotic events.[1-3] Despite the efficacy of DAPT, some patients still experience coronary thrombotic events (CTEs), such as myocardial infarction (MI), stent thrombosis (ST), revascularization, stroke, or even death. Therefore, identifying high-risk events in patients undergoing PCI and providing them with correct treatment are important.

The Patterns of non-Adherence to Anti-Platelet Regimen in Stented Patients (PARIS) thrombotic risk score[4] is a novel score for predicting the risks of out-of-hospital CTEs in patients undergoing PCI with drug-eluting stents (DESs). In previous studies, a clinical score, such as the Global Registry of Acute Coronary Events score, was often evaluated in different population, different end points, and different follow-up times.[5-7] In our previous study,[8] in a real-world population, we validated the predictive value of PARIS thrombotic score for CTEs in Chinese

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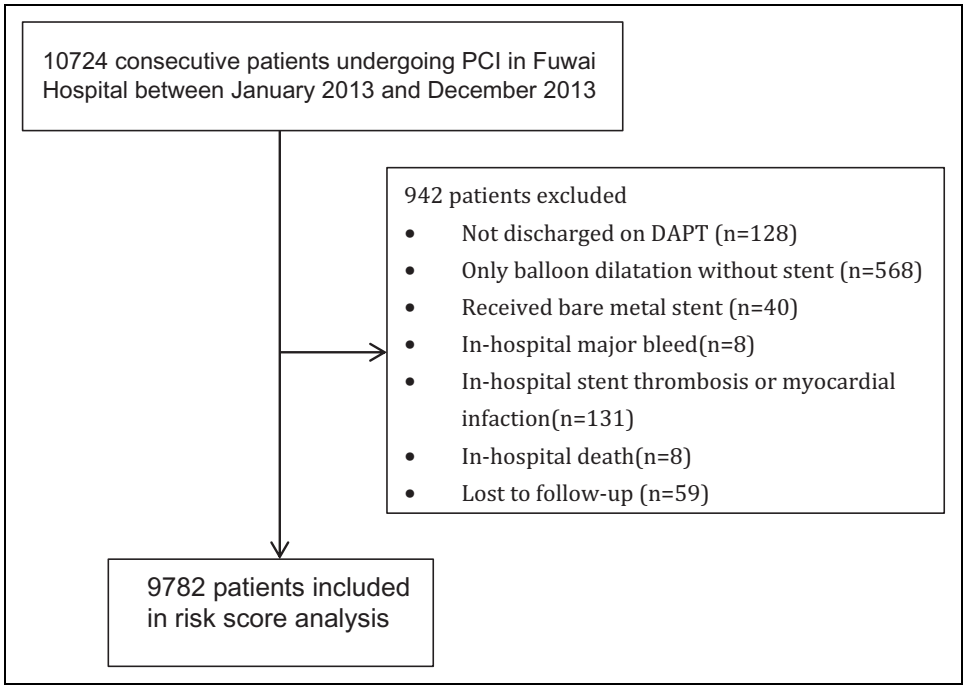

Figure 1. Flow chart of the study cohort. DAPT indicates dual-antiplatelet therapy; PCI, percutaneous coronary intervention.

patients after PCI. In addition to CTEs, death is a more serious cardiovascular event after PCI. However, the prognostic value of the PARIS thrombotic risk score for mortality and major adverse cardiovascular and cerebrovascular events (MACCE) has never been evaluated. Therefore, we aimed to evaluate the PARIS thrombotic risk score's predictive value for mortality and MACCE in a large sample in China.

Patients and Methods

Study Design

This was a prospective, single-center (Fu Wai Hospital, National Center for Cardiovascular Diseases, Beijing, China), observational study. Data from all consecutive patients who underwent PCI were collected between January 2013 and December 2013, as previously described.[9,10] A total of 10 724 patients were enrolled. To be consistent with the PARIS inclusion and exclusion criteria, we excluded the following: patients who were not discharged with DAPT; only balloon dilatation without stents; patients who did not successfully receive DESs; in-hospital major bleeding occurred, ST, MI, or death occurred; or patients who were lost to follow-up. After these exclusions, 9782 patients were included in the final analysis (Figure 1). After PCI, aspirin was prescribed at a dose of 100 mg daily indefinitely. Clopidogrel 75 mg daily or ticagrelor 90 mg twice daily was advised for at least 1 year.

Definitions and End Points

The PARIS thrombotic risk score in this study was compiled according to the risk score for CTE from PARIS.[4] The PARIS thrombotic risk score for CTE consisted of 6 factors, including acute coronary syndrome (ACS), current smoking, diabetes mellitus, creatinine clearance < 60 mL/min, prior PCI, and prior coronary artery bypass grafting (CABG). Death was defined as all-cause death. Major adverse cardiovascular and cerebrovascular events were defined as all-cause death, MI, revascularization, ST, or stroke during follow-up. Revascularization was defined as unplanned repeated revascularization for ischemic symptoms and events caused by PCI or surgery of any vessel. Creatinine clearance was calculated by using the Cockcroft-Gault formula.

Follow-Up

All patients were evaluated by clinic visit, phone, letter, or messages at 30 days, 6 months, 12 months, and 24 months through the Fuwai Hospital Follow-Up Center. Follow-up was performed via telephone in the PARIS study. Patients were advised to return to the hospital for coronary angiography if clinically indicated by symptoms or documentation of MI. All adverse events were conducted and adjudicated centrally by 2 independent cardiologists, and disagreement was resolved by consensus. All antiplatelet drugs use was also recorded in detail.

Ethical Approval

The study was conducted in accordance with the *Declaration of Helsinki* and was approved by the local ethics committee of Fuwai Hospital's Research Ethics Committee (No. 2013-449). The Institutional Review Board approved the study protocol and all of the patients provided written informed consent.

Table 1. Baseline Clinical Characteristics of Patients With Versus Those Without Death or MACCE.[a]

	Death	Survival	Statistics	*P* Value	MACCE	No MACCE	Statistics	*P* Value
N	97	9685			1002	8780		
Age, years, Mean (SD)	65.19 (10.56)	58.16 (10.18)	−6.76[b]	<.001	58.80 (10.48)	58.16 (10.18	−1.88[b]	.06
Female	12 (12.37)	2224 (22.96)	6.11[c]	.01	193 (19.26)	2043 (23.27)	8.19[c]	.004
BMI, kg/m^2, Mean (SD)	25.05 (3.24)	25.95 (3.18)	2.76[b]	.01	25.90 (3.16)	25.94 (3.18)	0.40[b]	.69
PARIS thrombotic risk score, Mean (SD)	3.27 (1.95)	2.54 (1.70)	−3.69[b]	<.001	2.80 (1.78)	2.51 (1.69)	−4.79[b]	<.001
Clinical presentation			0.43[c]	.81			0.30[c]	.86
Stale CHD	38 (39.18)	3877 (40.03)			394 (39.32)	3521 (40.10)		
Tropin-negative ACS	44 (45.36)	4114 (42.48)			428 (42.71)	3730 (42.48)		
Troponin-positive ACS	15 (15.46)	1694 (17.49)			180 (17.96)	1529 (17.41)		
Hypertension	70 (72.16)	6204 (64.06)	2.74[c]	.10	664 (66.27)	5610 (63.90)	2.20[c]	.14
Diabetes mellitus								
Non diabetes mellitus	59 (60.82)	6803 (70.24)	2.74[c]	.09	664 (66.27)	6198 (70.59)	9.17[c]	.01
Noninsulin-treated	27 (27.84)	1885 (19.46)			213 (21.26)	1699 (19.35)		
Insulin-treated	11 (11.34)	997 (10.29)			125 (12.48)	883 (10.06)		
Current smoking	59 (60.82)	5532 (57.12)	0.54[c]	.46	596 (59.48)	4995 (56.89)	2.46[c]	.12
Dyslipidemia	67 (69.07)	6512 (67.24)	0.15[c]	.70	706 (70.46)	5873 (66.89)	5.20[c]	.02
Previous MI	31 (31.96)	1809 (18.68)	11.09[c]	.001	208 (20.76)	1632 (18.59)	2.76[c]	.10
Previous PCI	36 (37.11)	2278 (23.52)	9.82[c]	.002	265 (26.45)	2049 (23.34)	4.82[c]	.03
Previous CABG	7 (7.22)	381 (3.93)	2.72[c]	.10	54 (5.39)	334 (3.80)	5.93[c]	.02
Previous stroke	18 (18.56)	1024 (10.57)	6.43[c]	.01	132 (13.17)	910 (10.36)	7.46[c]	.01
Previous vascular disease	24 (24.74)	1198 (12.37)	13.45[c]	<.001	153 (15.27)	1069 (12.18)	7.88[c]	.01
Anemia	9 (9.28)	326 (3.37)	10.15[c]	.001	36 (3.59)	299 (3.41)	0.10[c]	.76
CrCl < 60 mL/min	18 (19.15)	1065 (11.42)	5.46[c]	.02	121 (12.60)	962 (11.38)	1.28[c]	.26
Heart rate>100 beat/min	4 (4.12)	90 (0.93)	10.29[c]	.001	11 (1.10)	83 (0.95)	0.22[c]	.64
Systolic BP < 90 mm Hg	0 (0.00)	22 (0.23)	0.22[c]	.64	2 (0.20)	20 (0.23)	0.03[c]	.86
ST deviation	25 (25.77)	2081 (21.49)	1.04[c]	.31	229 (22.85)	1877 (21.38)	1.16[c]	.28
Congestive heart failure	7 (7.53)	178 (1.88)	15.52[c]	<.001	29 (2.94)	156 (1.82)	5.94[c]	.02
Abnormal myocardial enzyme	20 (20.62)	2081 (21.49)	0.04[c]	.84	217 (21.66)	1884 (21.46)	0.02[c]	.89

Abbreviations: BMI, body mass indexes; BP, blood pressure; CABG, coronary artery bypass grafting; CrCl, creatinine clearance; CHD, coronary heart disease; MACCE, major adverse cardiovascular and cerebrovascular events; MI, myocardial infarction; PARIS, Patterns of non-Adherence to Anti-Platelet Regimen in Stented Patients; PCI, percutaneous coronary intervention; SD, standard deviation; ST, stent thrombosis.

[a]Values are mean (SD) or n (%).

[b]*t* values.

[c]χ^2 values.

Statistical Analysis

Categorical variables are expressed as frequency (percentage) and continuous variables are expressed as mean (standard deviation). Mean levels of continuous variables with a normal distribution were compared by the Student *t* test. Pearson χ^2 test or Fisher exact test was used to compare categorical variables. Hazard ratios (HRs) and 95% confidence intervals (CIs) were computed by Cox proportional hazard models. The predictive value of the PARIS thrombotic risk score was assessed by the area under the receiver operating characteristic curve (AUROC). The *Z* test was used to compare AUROC values of 2 curves. All statistical analyses were performed at a significance level of 2-sided 0.05. Statistical analysis was performed with SAS version 9.2 software (SAS Institute, Cary, North Carolina).

Results

Patients' Characteristics

Among 10 724 patients who underwent PCI, 9782 patients were included in the final analysis after excluding patients who failed to satisfy the inclusion criteria (Figure 1). Baseline characteristics are shown in Table 1 (mean age: 58.23 [10.21] years, female sex: 22.9%). There were 5867 patients with ACS (including unstable angina pectoris and acute MI), which accounted for 60% of the total population. Only 13 patients took ticagrelor (0.13%) and the remaining patients took clopidogrel (99.87%); 96.4% of patients insisted on taking dual antiplatelet therapy at 1 year follow-up, and the mean duration of DAPT was 551.03 (162.92) days.

At the 2-year follow-up, 97 (0.99%) patients experienced death events and 1002 (10.24%) patients had MACCE. Patients with death events were characterized by an older age ($P <$ .001), male predominance ($P = .01$), a lower body mass index ($P = .01$), more frequent previous history of MI ($P = .001$), stroke ($P = .01$), peripheral vessel disease ($P < .001$) and previous PCI treatments ($P = .002$), and higher rates of anemia ($P = .001$), creatinine clearance rate of < 60 mL/min ($P = .02$), and heart failure and a heart rate of > 100 times/min ($P = .001$). Among the patients with MACCE, there were significantly higher rates of male sex ($P = .004$), diabetes ($P = .01$), hyperlipemia ($P = .02$), a previous history of stroke ($P = .01$), and

Table 2. Risk Stratification of the PARIS Thrombotic Risk Score.

	Death			MACCE		
	Hazard Ratio (95% CI)	χ^2	*P* Value	Hazard Ratio (95% CI)	χ^2	*P* Value
All patients			–			
Low (≤2)	Reference		–	Reference		–
Intermediate (3-4)	1.38 (0.87-2.18)	1.85	.17	1.11 (0.97-1.28)	2.19	.14
High (≥5)	2.31 (1.39-3.86)	10.36	.001	1.42 (1.20-1.69)	15.84	<.001
Non-ACS patients						
Low (≤2)	Reference		–	Reference		–
Intermediate (3-4)	2.49 (1.23-5.03)	6.43	.01	1.37 (1.10-1.71)	7.91	.005
High (≥5)	4.26 (1.75-10.35)	10.22	.001	1.68 (1.20-2.36)	9.29	.002
ACS patients						
Low (≤2)	Reference		–	Reference		–
Intermediate (3-4)	0.91 (0.50-1.67)	0.08	.77	0.97 (0.81-1.16)	0.10	.75
High (≥5)	1.69 (0.90-3.16)	2.67	.10	1.30 (1.06-1.60)	6.12	.01

Abbreviations: ACS, acute coronary syndrome; CI, confidence interval; MACCE, major adverse cardiovascular and cerebrovascular events; PARIS, Patterns of non-Adherence to Anti-Platelet Regimen in Stented Patients.

Table 3. Receiver Operating Characteristic Curves of Events According to the PARIS Thrombotic Risk Score in the Total Population and in Subgroups of Non-ACS and ACS Patients.

	Total Population		Non-ACS Patients		ACS Patients	
	AUC (95% CI)	*P* Value	AUC (95% CI)	*P* Value	AUC (95% CI)	*P* Value
Death	0.61 (0.55-0.66)	<.001	0.67 (0.58-0.75)	<.001	0.57 (0.49-0.64)	.09
MACCE	0.54 (0.53-0.56)	<.001	0.56 (0.53-0.59)	<.001	0.53 (0.51-0.56)	.011

Abbreviations: ACS, acute coronary syndrome; AUC, area under the curve; CI, confidence interval; MACCE, major adverse cardiovascular and cerebrovascular events; PARIS, Patterns of non-Adherence to Anti-Platelet Regimen in Stented Patients.

peripheral vessel disease ($P = .01$). Additionally, more patients with MACCE experienced heart failure and received previous PCI ($P = .03$) or CABG ($P = .02$) previously.

Patterns of non-Adherence to Anti-Platelet Regimen in Stented Patients Thrombotic Risk Score in the Death and MACCE Groups

The PARIS thrombotic risk score was significantly higher in the death group than in the survival group (3.27 [1.95] vs 2.54 [1.70], $P < .001$). The PARIS thrombotic risk score was also significantly higher in patients with MACCE than in those without MACCE (2.80 [1.78] vs 2.51 [1.69], $P < .001$).

Risk Stratifications of the PARIS Thrombotic Risk Score

For death, according to risk stratification of the PARIS thrombosis risk score, the score was categorized as low risk (0-2), intermediate risk (3-4), and high risk (≥5). The mortality risk in the high-risk group was 2.31 times higher than that in the low-risk group (HR, 2.31; 95% CI, 1.39-3.86; $P = .001$). However, the mortality risk in the intermediate- and low-risk groups was not significant (HR, 1.38; 95% CI, 0.87-2.18; $P = .17$; Table 2).

For MACCE, the PARIS thrombotic risk score in the high-risk group was significantly higher than that in the low-risk group (HR, 1.42; 95% CI, 1.2-1.69; $P < .001$). However, there was no significant difference in the PARIS thrombotic risk score between the intermediate-risk and low-risk groups (HR, 1.11; 95% CI, 0.97-1.28; $P = .14$; Table 2).

Predictive Value of the PARIS Thrombotic Risk Score

For mortality, the PARIS thrombotic risk score showed predictive value in the overall population (AUROC, 0.61; 95% CI, 0.55-0.66; $P < .001$). In further analysis, the PARIS thrombotic risk score showed predictive value in the non-ACS population (AUROC, 0.67; 95% CI, 0.58-0.75; $P < .001$), but showed no significant difference in the ACS population (AUROC, 0.57; 95% CI, 0.49-0.64; $P = .09$; Table 3).

For MACCE, the PARIS thrombotic risk score showed predictive value in the overall population (AUROC, 0.54; 95% CI, 0.53-0.56; $P < .001$), non-ACS population (AUROC, 0.56; 95% CI, 0.53-0.59; $P < .001$), and ACS population (AUROC, 0.53; 95% CI, 0.51-0.56; $P = .01$; Table 3). The PARIS thrombotic risk score for the predictive value of mortality (AUROC: 0.61) was higher than that of MACCE (AUROC: 0.54), ($Z = 2.09$; $P = .04$; Figure 2).

Discussion

In this study of 9782 patients who underwent PCI with DESs, we evaluated the predictive value of the PARIS thrombosis risk

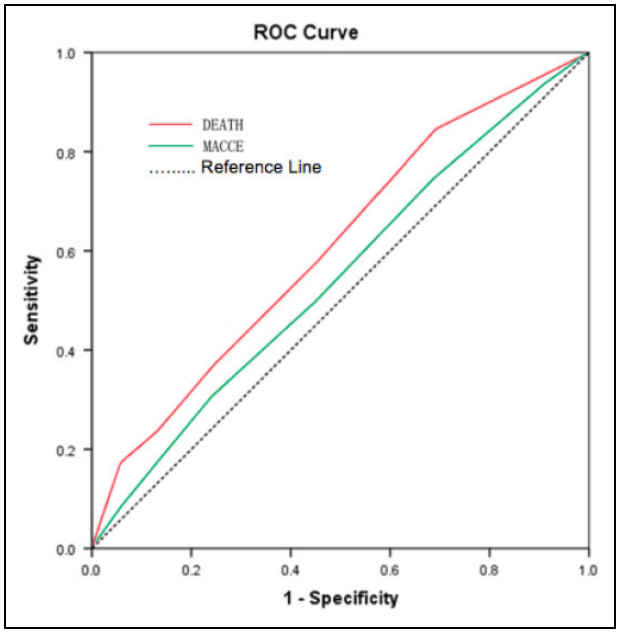

Figure 2. Predictive value of the PARIS thrombotic risk score for mortality and MACCE. The PARIS thrombotic risk score showed predictive value for mortality (AUROC, 0.61) and MACCE (AUROC, 0.54). The prognostic value of mortality was higher than that of MACCE ($Z = 2.09$, $P = .04$). AUROC indicates area under the receiver operating characteristic curve; MACCE, major adverse cardiovascular and cerebrovascular events; PARIS, Patterns of non-Adherence to Anti-Platelet Regimens in Stented Patients.

score for mortality and MACCE. We found the following results. First, the PARIS thrombotic risk score was significantly higher in the death group and MACCE group than that in the no events group. Second, according to risk stratification of the PARIS thrombosis risk score, the mortality and MACCE risks of patients in the high-risk group were significantly higher than those in the low-risk group. Third, the PARIS thrombotic risk score had moderate clinical value for predicting the risk of mortality and limited value for MACCE, and the prognostic value of mortality was better than that of MACCE.

In our study, although patients with coronary heart disease were treated with DESs and DAPT, 0.99% of patients still died and 10.24% of patients experienced MACCE during the 2-year follow-up. The PARIS thrombotic risk score was significantly higher in the event group than in the event-free group. Next, our results indicated that according to risk stratification of the PARIS thrombotic risk score, this score could identify those with a high risk of death and MACCE from patients with a low risk. This finding indicated that the PARIS thrombotic risk score could contribute to identifying populations with a high risk of death and MACCE events. This indicates a good clinical practice value. Identifying these high-risk patients by the PARIS thrombotic risk score will help clinicians to strengthen monitoring and treatment to decrease the incidence of adverse events after DESs.

The PARIS thrombosis risk score[4] was mentioned in the 2017 DAPT guidelines,[11] which is a novel score for predicting the risks for out-of-hospital CTEs after PCI with DESs. In previous studies, a clinical score was often evaluated repeatedly in the real world, including for different populations, different end points, or different follow-up time. As far as we know, the PARIS thrombosis risk score has not been used to evaluate the predictive value of mortality and MACCE. Death is the most serious adverse prognosis after PCI. For the first time, we used a large sample (9782 patients) of real-world studies to evaluate the predictive value of this new score for death in patients with PCI and to obtain positive results. Our exploratory study showed that the PARIS thrombosis score had moderate predictive value for mortality (AUROC, 0.61) and limited value for MACCE (AUROC, 0.54). This result will help clinicians to have a more comprehensive understanding of the score and provides evidence for a wider range of applications of the PARIS thrombotic risk score. The content of the PARIS thrombosis score is relatively simple, including only 6 factors, and it is easy to calculate and convenient for clinical use. Clinicians can use the PARIS thrombotic risk score not only to predict the risk of CTEs, but also to assess the risk of mortality and MACCE for patients after PCI. A possible reason why PARIS thrombotic risk can also predict mortality and MACCE might be contribute by major predictors used in PARIS thrombosis risk score, including diabetes,[12-14] ACS diagnosis,[15,16] current smoking,[17-19] decreased creatinine clearance rate,[20,21] previous PCI,[22] and CABG,[23,24] such predictors were also previously reported to be risk factors for a poor prognosis of coronary heart disease.

To date, the risk scores for coronary heart disease, including the Global Registry of Acute Coronary Events score,[5,25] Thrombolysis in Myocardial Infarction score,[20]Platelet glycoprotein IIb/IIIa in Unstable angina: Receptor Suppression Using Integrilin (eptifibatide) Therapy score,[26] and the Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications score,[27] are mainly used in the ACS population for predicting mortality in a short time. The overall National Cardiovascular Data Registry model[28] was reported to have excellent predictive value for estimating 30-day mortality rates in patients with PCI, but there were no long-term follow-up results. Our study is the first to propose the PARIS thrombotic risk score as a new potential useful score for predicting long-term mortality and MACCE in patients after PCI with DESs. In further analysis for mortality, the PARIS thrombotic risk score showed significant predictive value in the non-ACS population (AUROC, 0.67), but no significant difference in the ACS population (AUROC, 0.57). Because this was a subgroup analysis, further research is required in the future for a large-sample study of patients with ACS. For MACCE, the PARIS thrombotic risk score showed predictive value in the overall population, non-ACS population, and ACS population. These findings indicate that the PARIS thrombosis score has certain clinical practical value in patients with ACS and non-ACS patients for MACCE.

Our study suggests clinical practice value for the PARIS thrombotic risk score, and provides evidence for a wider range of applications of this score. However, although the PARIS

thrombotic risk score has predictive value for mortality and MACCE after PCI, its value is relatively limited. In the future, we need to establish a new risk score, or add biomarkers to the PARIS thrombotic risk score to improve this score's predictive value.

Limitations

Some limitations of our analysis should be considered. First, our study was a single-center, observational study, which may have limited its generalizability. Second, most patients took clopidogrel (99.87%) in our study, and there is no further analysis of the loading dose of antiplatelet drugs, therefore further study is needed to elucidate these issues.

Conclusion

In conclusion, our real-world, large-sample study shows that according to risk stratification of the PARIS score, the PARIS thrombotic risk score can contribute to identifying populations with a high risk of death and MACCE. The PARIS thrombotic risk score has modest, long-term, out-of-hospital prognostic value for mortality and MACCE in patients undergoing PCI. The prognostic value of mortality is better than that of MACCE.

Authors' Note

X.Y.Z., Y.X., J.C., S.B.Q., Y.J.Y., R.L.G., B.X., and J.Q.Y. contributed to the conception or design of the work. J.X.L., X.F.T., Z.G., L.J.G., and L.J. contributed to the acquisition, analysis, or interpretation of data for the work. X.Y.Z. drafted the manuscript. Y.X., B.X., and J.Q.Y. critically revised the manuscript. All gave final approval and agree to be accountable for all aspects of work ensuring integrity and accuracy.

Declaration of Conflicting Interests

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